UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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MEMORANDUM

SUBJECT: **Paraquat:** Response to Comments on the EFED Preliminary Ecological Risk Assessment for Registration Review

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The Environmental Fate and Effects Division (EFED) reviewed comments from the technical registrant, Syngenta, and from Beyond Pesticides, Center for Biological Diversity, City of Sacramento Department of Utilities, National Agricultural Aviation Association (NAAA), and Washington State Department of Agriculture, on the "Paraquat: Preliminary Ecological Risk Assessment for Registration Review" (DP430829, Docket ID EPA-HQ-OPP-2011-0855). The purpose of this memorandum is to respond to these comments. The comments are copied or summarized below and followed by responses from EFED.

Comments on "Paraquat Dichloride: Preliminary Ecological Risk Assessment for Registration Review," hereafter called PRA (preliminary risk assessment) and EPA Responses

Syngenta Comments (comments from p. 31-59 of comment submission):

EPA-HQ-OPP-2011-0855-0128	EPA Statement
Page 4 Overall conclusions 1.2 Risk Conclusions Summary	It is largely unknown when or if paraquat applications might exceed the adsorptive capacities of the soil/sediment and whether or how fast the excess paraquat would metabolize in the environment.
-- Page 7 Uncertainties with Modeling Estimates	-- There is little fate data available to characterize how paraquat behaves in the environment after soil or sediment adsorption sites become saturated. Based solely on its lack of halogenation and absence of complex ring structures, it is reasonable to infer that any bioavailable (non-adsorbed) paraquat would be readily metabolized.

1. **Syngenta Comment (p. 4-7 of PRA):** In a review of the long-term environmental fate of paraquat in soil, Roberts *et al.* (2002) describes a strong adsorption capacity-wheat bioassay (SACWB) method that they deemed valuable for determining the adsorption capacity of paraquat in different types of soil. The SAC-WB method was utilized in a series of longterm trials in different regions of the world and the resulting data indicate that following repeated applications to very high levels of paraquat in the field, residues not only plateaued, but ultimately declined, which demonstrates that biodegradation of paraquat in soil pore water is important for field dissipation. These trials indicate that repeated use of paraquat in field will have no detrimental effects on soil-dwelling fauna nor flora/crops after paraquat is adsorbed to soils. Overall, the review by Roberts *et al.* (2002) provides strong evidence that under realistic agricultural use patterns, paraquat is unlikely to exceed the adsorptive capacities of soil/sediment. There is also substantial research demonstrating that paraquat is intrinsically biodegradable by soil microorganisms (Funderburk and Bozarth 1967, Summers 1980, Dyson 1997, and Ricketts 1998). The aforementioned information is useful for addressing the uncertainties concerning some of the modeling estimates.

   EPA Response: The Agency appreciates the information and references and will consider them in future assessments.

EPA-HQ-OPP-2011-0855-0128	EPA Statement
Page 11	Use sites include terrestrial food, nonfood, feed, forestry, residential, commercial, and nursery use sites, as well as some indoor use patterns.

2. **Syngenta Comment (p. 11 of PRA):** Paraquat products are prohibited from use in residential or nonoccupational settings and should not be included in the list of allowed uses. Syngenta paraquat products (Gramoxone SL 2.0 and Gramoxone SL 3.0) explicitly state:

"NEVER USE THIS PRODUCT IN RESIDENTIAL OR PUBLIC RECREATIONAL SETTINGS (E.G., HOMES, HOME GARDENS, SCHOOLS, RECREATIONAL PARKS, GOLF COURSES, AND/OR PLAYGROUNDS)".

EPA Response: The Agency agrees that the residential use should not have been included in the use description of the assessment and was not assessed.

EPA-HQ-OPP-2011-0855-0128	EPA Statement
Page 11 3.2 Label and Use Characterization 3.2.1 Label Summary --------------------------- Table 3-1. Paraquat Use Sites and Application Characteristics	Many of the current labels do not contain sufficient information to limit maximum annual numbers of applications or maximum annual application rates and do not specify the minimum retreatment intervals. The highest application rates and shortest minimum application interval appropriate for the use are used in the exposure assessment.

3. **Syngenta Comment (p. 11 of PRA):** The use patterns on most of the currently registered paraquat labels are identical to and appear to have been based upon the use patterns approved over the long use history of paraquat containing products for weed control. The use patterns on these labels reflect the label requirements at the time the use pattern was registered and have been reassessed during multiple Agency reviews. As noted in the Agency's comment, "Many of the current labels do not contain sufficient information to limit maximum annual numbers of applications or maximum annual application rates and do not specify the minimum retreatment intervals." An exception to this is the newly registered Gramoxone 3LB product (EPA Reg. No. 100-1652). While this registration did not add any new uses, Syngenta proactively did a major revision of the label format including updating the use directions to provide with respect to each use pattern clear information including Maximum Single Application Rate, Maximum Annual Rate, Minimum Application Intervals (where appropriate), Re-entry Intervals and Pre-Harvest Intervals. This label therefore does contain the information that the Agency has identified as missing on "many of the current labels".

   It should be noted that in addition to the newly registered Gramoxone 3LB, Syngenta also has a registration for the paraquat product Gramoxone SL 2.0 (EPA Reg. No. 100- 1431) for which we have not made the above indicated label revisions. This product, which is currently undergoing phase III label reviews in accordance with the Paraquat Human Health Mitigation Decision, will be phased out and replaced by Gramoxone 3LB once all state registrations have been obtained for Gramoxone 3LB. Syngenta also has a paraquat plus S-metolachlor pre-mix product pending registration (Gramoxone Magnum EPA Reg. No. 100-RAUR). The label for this product has also been structured in the same updated format as Gramoxone 3LB including containing the information that the Agency has identified as missing on "many of the current labels". As such, the Gramoxone 3LB and the pending Gramoxone Magnum labels are representative of the labelling approach for Syngenta paraquat products moving forward while the older labelled product, Gramoxone SL 2.0, will be phased out.

   EPA Response: The Agency appreciates the work that has been and is being done to improve labels, which will lead to greater certainty in future assessments. In addition, EPA is proposing standardized use directions across all labels (to include Maximum Single Application Rate, Maximum Annual Rate, Minimum Application Intervals (where appropriate), Re-entry Intervals and Pre-Harvest Intervals in its Proposed Interim Decision).

EPA-HQ-OPP-2011-0855-0128	EPA Statement
Section 3.2.1 Page 11	Label Summary Table 3-1. Paraquat Use Sites and Application Characteristics

4. **Syngenta Comment (p. 11 of PRA):** While Table 3-1 summarizes the application characteristics for approved uses including the application type and maximum single application rates, for most of the uses, the yearly maximum application rate (paraquat cation (PQ+)/A/year) and minimum retreatment intervals are not specified. As noted by the Agency and discussed in the previous point, many of the current paraquat labels do not provide this information, however this information is specified in the use directions as well as summarized in section 12.2 of the Gramoxone 3LB label approved on September 29, 2019. Syngenta has included Appendix 1 in these comments which provides a comparison of the use patterns identified by the Agency Table 3-1 with the corresponding use patterns as approved on the Gramoxone 3LB label.

   As shown in Appendix 1, the maximum single application rate Syngenta supports is no more than 1 lb PQ+ per acre. The 1 lb PQ+/A single application rate provides effective control and the higher rate is not needed for non-selective weed control or desiccation. The Agency has included in the preliminary risk assessments a maximum rate of 1.5 lb PQ+/A for alfalfa and clover which exceeds the maximum allowed use rate allowed or supported for any Syngenta paraquat product.

   EPA Response: It is Agency policy to assess the application rate, number of applications, and minimum retreatment interval that lead to the highest exposure values for each use. The 1.5 PQ+/A application rates were on three active special local needs registrations at the time the assessment was conducted, for Colorado (alfalfa – Reg # CO170001), Idaho (clover – Reg # ID080009) and Wyoming (alfalfa and clover – Reg # WY140004). While these procedures ensure a conservative assessment, they do not acknowledge the differences between individual labels of the same use. In addition to evaluating the highest potential exposure, the PRA includes calculations of RQs for both aquatic and terrestrial organisms at 1.0 lb PQ+/A for "multiple ag and non-ag uses" that can be applied to the Section 3 labeled rates for alfalfa and clover. In general, the risk conclusions were similar for the two rates. While the same taxa were identified as being at risk with the two rates, some details were different. For example, more bee castes had risk concerns at the higher rate, while the lower rate had some higher risk quotients for birds and mammals because more applications are allowed at the lower rate. More detail can be found in the assessment.

EPA-HQ-OPP-2011-0855-0128	EPA Statement
Page 19	The freshwater diatom (Navicula pelliculosa) was approximately three orders-of-magnitude more sensitive than the marine diatom (Skeletonema costatum), with respective EC50 and NOAEC of 0.40 and 0.16 µg cation/L (MRID 42601006). Data were available for eight algal species, including 2 marine species and one cyanobacterium.

5. **Syngenta Comment (p. 19 of PRA):** Species Sensitivity Distributions (SSD) are a higher tier risk assessment tool often applied for assessing potential effects at the community level. Aquatic ecosystems generally exhibit "functional redundancy or compensation" (Baskin, 1994; Moore, 1998; Diaz and Cabido, 2001; Peterson et al., 1998; Rosenfeld, 2002; Loreau, 2004), which implies that

multiple species are present in an ecosystem to perform each critical function (Rosenfeld, 2002). Thus, it is the collective vascular and non-vascular plant assemblage, rather than a single species that drives ecosystem functions. While Syngenta understands that the current EPA screening level risk assessment paradigm focuses on the most sensitive species for a taxonomic group, an examination of additional species hazard data and the use of Species Sensitivity Distributions (SSD) approach may prove informative for higher tier risk assessments and/or risk management decisions. This may be particularly relevant for paraquat as there is a wide range of non-vascular plant endpoints ranging from *Navicula* EC50 = 0.40 µg PQ+/L (MRID 42601006) to *Chlorococcum* EC50 = 36,000 µg PQ+/L (MRID 40228401).

An SSD was developed for non-vascular plants exposed to paraquat. Vascular plants were not considered in the SSD because no LOC exceedances were identified in the EPA preliminary ecological risk assessment. Data used to generate the non-vascular plant SSD were compiled from Appendix B, Table B-3 of the EPA preliminary ecological risk assessment for paraquat. EC/IC50 values were used because they were available for each species. The SSD was assembled using the ssdtools package in R (https://bcgov.github.io/ssdtools/), which examines multiple distributions to estimate an average fit based on the relative weights of each distribution (Burnham and Anderson 2002). The summary of each distribution fit is provided in Table 4 and visualized in Figure 3, and the average fit is shown in Figure 4.

Table 4. Summary of multiple species sensitivity distribution fits for non-vascular plants exposed to paraquat.

Distribution	AD	KS	CVM	AIC	AICc	BIC	Delta	Weight
lnorm	0.47	0.25	0.08	150.91	153.31	151.07	3.38	0.10
llog	0.41	0.20	0.06	151.14	153.54	151.29	3.60	0.09
lgumbel	0.61	0.26	0.11	153.50	155.90	153.66	5.96	0.03
gamma	0.18	0.15	0.03	147.53	149.93	147.69	0.00	0.51
weibull	0.30	0.19	0.04	148.74	151.14	148.90	1.20	0.28

AD: Anderson-Darling statistic; KS: Kolmogorov-Smirnov statistic; CVM: Cramer-von Mises statistic; AIC: Akaike's Information Criterion; AICc: Akaike's Information Criterion corrected for sample size; BIC: Bayesian Information Criterion, Delta: The Information Criterion differences; Weight: The Information Criterion weights

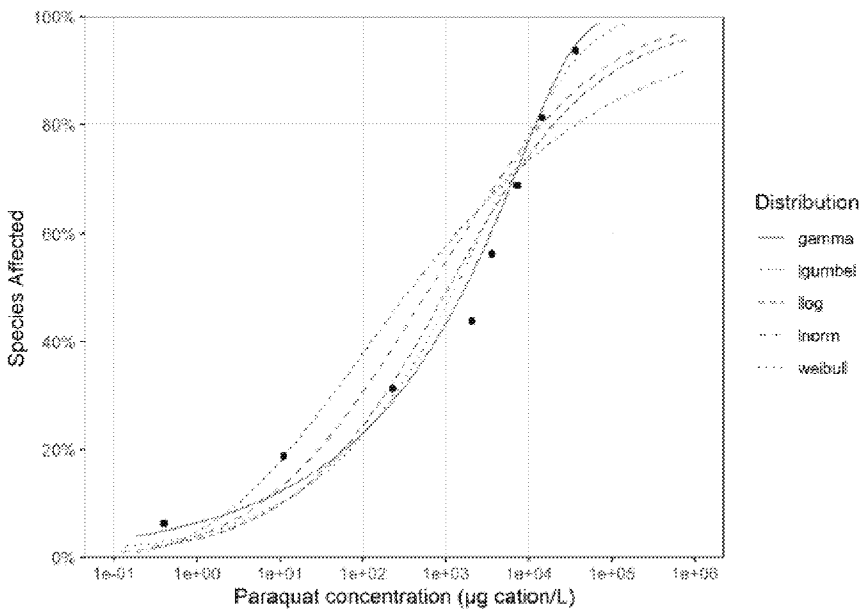

Figure 3. Multiple species sensitivity distribution fits for non-vascular plants exposed to paraquat.

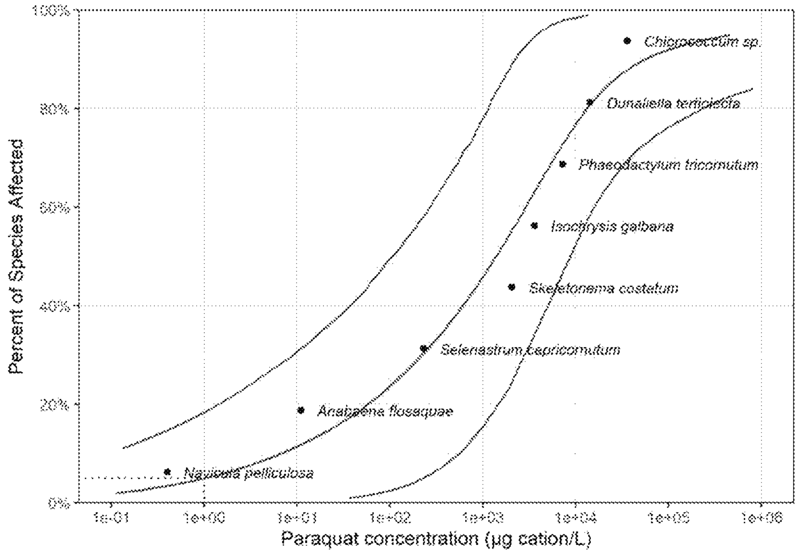

Figure 4. Average species sensitivity distribution fit for non-vascular plants exposed to paraquat. The green lines denote upper and lower confidence levels, and the dotted line identifies the HC5 (concentration affecting 5 percent of species).

Using the SSD approach, the HC5 (concentration affecting 5 percent of species) was estimated to be 0.998 µg PQ+/L.

EPA Response: The selection of an endpoint with which to describe the potential risk from exposure to paraquat is a matter of science policy. While EPA acknowledges that the SSD approach is one way to evaluate the toxicity of a pesticide or family of pesticides and this approach is used when warranted, the Agency does not agree that use of a toxicity threshold from an SSD is a more correct expression of potential risk to organisms than use of the most sensitive endpoint for each taxon. Rather, use of the most sensitive endpoint is justified given the limited data available as compared to the species the data are expected to represent.

The Agency recognizes that functional redundancy exists in aquatic ecosystems and that the SSDs presented for paraquat indicate that some aquatic taxa appear to be less sensitive than others. Such information may help characterize risk for higher tier risk assessments and/or risk management decisions. The Agency acknowledges that use of toxicity data from a small subset of organisms to screen for risk to a large, diverse set of organisms may not cover the range of sensitivities in natural ecosystems and that refinements can help inform some risk conclusions.

EPA-HQ-OPP-2011-0855-0128	EPA Statement
Section 6.2 Page 21 Page 23	Terrestrial Toxicity The LD50 for laboratory rats was 93 mg cation/kg-bw from a dosing study (MRID 43685001), but rats fed diets containing paraquat up to 108 mg cation/kg-diet for 138-weeks showed no measurable effects in reproductive or offspring body weight (MRID 00126783)." Table 6-2. Terrestrial Toxicity Endpoints Selected for Risk Estimation for Paraquat

6. **Syngenta Comment (p. 21-23 of PRA):** The 3-generation rat study (MRID 00126783) included diets containing paraquat up to 150 mg cation/kg-diet, not 108 mg PQ+/kg-diet. It appears the dietary concentration was incorrectly adjusted for cation concentration.

   EPA Response: The Agency thanks Syngenta for the clarification. The study report (MRID 00126783) shows a nominal dietary concentration of 150 ppm of paraquat ion in Table 1 with ranges given of 136-165 and 166-180 ppm for females and males, respectively, in the highest treatment. An adjusted endpoint of 108 mg cation/kg-diet was used in previous assessments. The 108 mg cation/kg-diet value came from adjusting 150 ppm (assuming 150 ppm is in units of mg paraquat dichloride a.i./kg) to mg paraquat cation/kg using the molecular wt. ratio of the dichloride form and the ion. The original study report copy quality is low but appears to support the nominal 150 mg cation/kg-diet concentration. If the nominal concentration of 150 mg cation/kg-diet is used as the NOAEC to screen for risk, and the results compared with those from 108 mg cation/kg-diet calculations, the risk conclusions change for 3 feeding guilds at each of the single application rates, but risk conclusions do not change for any of the guilds at the 1.01 lb cation/acre rate with multiple applications (applies to both 5 and 10 applications at 7-day intervals). The overall conclusions do not change substantially because acute and chronic dose-based levels of concern are also exceeded for most feeding guilds and size classes because risk could not be discounted for mammals in 4 out of 6 feeding guilds from a single application at the 1.01 lb cation/A rate and 3 out of 6 guilds at the 0.5 lb cation/acre rate. A revised **Table 9-4** from p. 61 of the PRA with revisions in red text can be found in **Appendix A** of this document.

EPA-HQ-OPP-2011-0855-0128	EPA Statement
Section 6.2 Page 23	Terrestrial Toxicity Table 6-2. Terrestrial Toxicity Endpoints Selected for Risk Estimation for Paraquat

7. **Syngenta Comment (p. 23 of PRA):** The acute bee studies (MRID 43942603) reported a 48-h acute contact LD50 = 72.4 µg paraquat cation (PQ+)/bee and 48 h acute oral LD50 = 31.0 µg PQ+/bee for the Gramoxone formulation, which was considered more sensitive than technical paraquat. Similarly, the data evaluation record (MRID 43942603) reported a 48-h acute contact LD50 = 75.9 µg PQ+/bee and acute oral LD50 = 29.9 µg PQ+/bee for the Gramoxone formulation (Table 5). In the

EPA preliminary ecological risk assessment for paraquat, it appears the dietary concentration was incorrectly adjusted for cation concentration.

Table 5. Summary of reported acute bee study endpoints.

Endpoint	EFED	Study report	DER
48-h acute oral LD50	22 µg PQ+/bee	31 µg PQ+/bee	29.9 µg PQ+/bee
48-h acute contact LD50	52 µg PQ+/bee	72.4 µg PQ+/bee	75.9 µg PQ+/bee

<u>EPA Response</u>: The DER (data evaluation record) for MRID 43942603 (from 1996) reported contact and oral LD_{50}s of 72 and 31 µg a.i./bee, respectively. Endpoints were adjusted from paraquat dichloride a.i. to paraquat cation based on molecular weights, using a conversion factor of 0.724294 (186.259/257.158 g/mol). This resulted in contact and oral LD_{50} endpoints of 52 and 22 µg cation/bee, respectively. The problem formulation (from December 12, 2011, DP392076) also listed these values (52 and 22 µg cation/bee) on p. 66. These were the values used in the assessment.

However, a check of the original study report for MRID 43942603 showed that the concentrations were already adjusted for paraquat cation and therefore the contact and oral LD_{50}s should have been 72 and 31 µg cation/bee, respectively. An amendment will be generated to clarify the DER. The corrected endpoints do not, however, change the risk conclusions except for one caste, workers comb building, cleaning and food handling, which dropped below the LOC of 0.4 at the highest application rate of 1.5 lb/acre; also the distances needed to remove the presumption of risk were reduced somewhat. Using these values, the corrections excerpts from pages 6, 23, 69-73, 124, 162-164 for the assessment are found in **Appendix A** with corrections in red text.

EPA-HQ-OPP-2011-0855-0128	EPA Statement
Page 40-41	Acute water column exposure calculations

8. **Syngenta Comment (p. 40-41 of PRA):** Syngenta is submitting a fast track label amendment for Gramoxone 3LB that will address desired label changes and will include the following use restrictions:

For ground spray applications:
- requiring that ground applications NOT exceed a boom height of 24 inches above target pest or crop canopy
- applicators are required to use a coarse or larger spray quality (droplet size) according to ASABE Standard S572.2 for spray applications.

For aerial spray application:
- applicators are required to use a coarse or larger spray quality (droplet size) according to ASABE Standard S572.2 for spray applications.
- boom height up to 10 ft above the vegetative canopy (unless a greater application height is necessary for pilot safety)
- boom length must not exceed 65% of the wingspan for airplanes or 75% of the rotor blade diameter for helicopters
- applicators must use ½ swath displacement upwind at the downwind edge of the field
- do not apply when wind speeds exceed 10 miles per hour (mph)

Syngenta recalculated ground and aerial spray fractions based on the updated spray drift mitigation specified in the Gramoxone 3LB label and its amendment. For ground spray, Tier I AgDRIFT (version

2.1.1) spray drift exposure model was used with low boom height and droplet size distribution set to ASAE fine to medium/coarse, resulting in ground spray fraction of **0.011**. Tier I AgDRIFT does not account for specific droplet size of coarse or larger; therefore, the ground spray fraction of 0.011 would presumably be even lower if the model could account for coarse to coarser droplet size. For aerial spray, Tier II AgDRIFT (version 2.1.1) spray drift exposure model was used with boom height of 10 ft, boom length of 75% for aircraft except for helicopter (65%), droplet size distribution set to ASAE coarse to very coarse, swath displacement fraction of 0.5 and wind speed of 10 mph. Tier II AgDRIFT generated aerial spray fractions of 0.025, 0.028, **0.038** and 0.020 for air tractor AT-401, Ag Husky, Wasp helicopter, Air tractor AT-502 aircrafts, respectively.

Ground and aerial spray drift fractions of 0.011 and 0.038 (worst case), respectively, were applied to the acute exposure calculation provided on p.40 of the EPA preliminary ecological risk assessment for paraquat. The acute aquatic exposure values for various label (Gramoxone SL 3.0) application rates are presented below (Table 6). Acute exposure ranges from **0.12 to 2.13 µg/L**, significantly lower than those presented in the Table 8-3 on p. 40 (1.7-10.5 µg/L) of the EPA preliminary ecological risk assessment. These refined acute exposure values align with label spray drift mitigation and application rates; therefore, they should be used in the aquatic risk assessment.

Table 6. Acute (peak) exposure concentrations.

Application rate (lb PQ+/A)*	Application type (spray drift fraction)	Acute (peak) exposure (µg PQ+/L)
0.19 (special local use, wheat – ID only)	Aerial (0.038)	0.40
	Ground (0.011)	0.12
0.25 (lowest maximum single app. rate except for wheat – ID)	Aerial (0.038)	0.53
	Ground (0.011)	0.15
1.0 (highest maximum single app. rate)	Aerial (0.038)	2.13
	Ground (0.011)	0.62

PQ+ = paraquat cation

EPA Response: Registration Review assessments are done for all uses/labels that are registered at the time of the assessment. The Agency notes that Syngenta does not support an application rate of 1.5 lbs/acre. Application rates of 0.5 and 1.01 lb cation/acre were also assessed. If the changes as indicated by Syngenta were implemented on the label, the exposure would be lower and therefore could result in potentially lower risk to aquatic organisms. Preliminary calculations comparing the assessed rate of 0.5 lb/acre with the lower currently registered minimum rates of 0.25 and 0.19 lb/acre (50 and 38% lower, respectively) show that the lower rates change the risk picture for acute mammal risk and plant risk (to below levels of concern), but not for chronic mammal risk (highest RQs reduced from 6.9 to 3.5 and 2.6, respectively for the lower rates of 0.25 and 0.19 lb/acre) acute (highest RQs reduced from 4.9 to 2.5 and 1.9, resp.) and chronic bird risks (highest RQs reduced from 4.1 to 2.0 and 1.6, resp.), and bee risk (highest RQs reduced from 2.2 to 1.1 and 0.8, resp.). For those taxa, some feeding groups, size classes, and bee castes fall below the levels of concern, but not all. Additionally, any changes on the label will be considered for future assessments.

EPA-HQ-OPP-2011-0855-0128	EPA Statement
Page 41-44	Sediment Exposure Estimates

9. **Syngenta Comment (p. 41-44 of PRA):** Syngenta proposes refinements to sediment exposure estimates by:
1. Utilization of Kd value associated with soil type use in crop scenarios used in the assessment (MS Cotton and FL Turf)

2. Modifying erosion parameter (LS (length-slope) factor) in MS Cotton scenario such that average soil loss per year is sustainable (5 tons/acre/year)

As stated in sub-section 8.1.1 of the EPA paraquat preliminary ecological risk assessment for registration review, paraquat has high affinity for adsorption to soils. Paraquat has unique soil/sediment adsorption/desorption relationship where adsorption coefficient (Kd) varies depending on clay content and soil type, it does not follow the typical relationship modeled by the Agency's aquatic exposure models (constant Kd). However, Syngenta believes that such an approach would introduce additional uncertainty in EEC estimates. As an alternative, Syngenta proposes to use Kd relevant to soil type in crop scenarios modeled by the Agency rather than constant Kd for all soil types/crops scenarios modeled. Such an approach could provide greater ecological realism in the ecological risk assessment.

For **MS Cotton** scenario, the soil type is silt loam and appropriate Kd is **7,400 mL/g** (arithmetic mean of bounded values of 9,400 and 5,400 mL/g in Table 8-1, silty clay loam soil). For **FL Turf** scenario, the soil type is sand and appropriate Kd is **249.3 mL/g** (arithmetic mean of bounded values of 480, 200, 68 mL/g in table 8-1, sand soil).

MS Cotton scenario is one of the top 3 scenarios with highest average annual soil loss (34.48 tons/acre/year) among all standard scenarios in Pesticide Water Calculator (PWC) model. Maximum soil loss in any single simulated year is 97.0 tons/acre, every year simulated for the MS Cotton scenario exceeded 5 tons/acre/year soil loss. At this rate of soil loss (34.48 tons/acre/year), the field is considered unsustainable (the amount of soil loss per year exceeds the amount that the land can tolerate before it loses its ability to sustain a healthy crop). MS cotton scenario does not reflect agronomic conditions where growers would have to implement soil conservation practices in order to claim USDA benefits for complying with USDA National Resources Conservation Service (NRCS) conservation practices to substantially reduce erosion rates to longterm sustainable levels (1 ton/acre per year for shallow or fragile soils to 5 tons/acre per year for deep soils that are least subject to damage by erosion). Additionally, one of the benefits of paraquat is its use in conservation agriculture allowing for reduced tillage and no-tillage farming programs. The importance of these practices is demonstrated by a 2018 USDA survey that reported conservation tillage was used on roughly 70 percent of soybean (2012), 65 percent of corn (2016), 67 percent of wheat (2017), and 40 percent of cotton (2015) acres.(USDA 2018) Therefore, MS cotton standard scenario was modified to achieve average soil loss of 5 tons/acre/year by adjusting erosion parameter **LS (length-slope) factor** from the original 1.34 to **0.19**. This reduction of approximately 6.9 fold is equal to the reduction needed from the original soil loss of 34.48 tons/acre/year to sustainable soil loss to 5 tons/acre/year.

The table below (Table 7) presents estimated concentrations in sediment after thirty years based on refinements 1 and 2 above following the application information in the current label (Gramoxone 3LB):

- Cotton (MS Cotton): 1 lb paraquat cation (PQ+)/A/application x 3 applications/year, 7-day intervals
- General non-crop uses (FL Turf): 1 PQ+/A/application x 6 applications/year, 7- day retreatment interval

Table 7. Estimated pore water and sediment concentrations.

Scenario	Application type	Sediment burial	Pore water concentration EEC* (µg PQ+/L)		Sediment concentration EEC* (mg PQ+/kg)	
			EFED	Syngenta	EFED	Syngenta
MS Cotton	Aerial	Without	150	11.6	150	85.6
		With	7.18	2.59	7.18	19.2
FL Turf	Ground	Without	46.3	92.6	46.3	23.1
		With	46.3	92.6	46.3	23.1

*MS Cotton with burial reached steady state EECs and therefore EECs were 1-in-10-year concentration. For other scenarios, pore water and sediment EECs represented accumulated concentration that occurred at the end of 30 years.

USEPA provided estimated sediment EECs with and without sediment burial (Table 8- 5 of the paraquat USEPA preliminary ecological risk assessment (USEPA 2019). Syngenta advocates for the use of sediment burial, represented in PWC by a first-order removal of pesticide by flowing erosion-contributed sediment through and out of the benthic zone, to serve as refinement that may inform either the risk assessment or risk management decision. As noted earlier, in the presence of soil or sediment, paraquat rapidly and strongly adsorbs to soil/sediment (Kd values ranged from 68 to 50,000 mL/g depending on clay content and cation exchange capacity). Consequently, paraquat residues associated with pond sediments would be subject to burial. Syngenta's understanding is the FL Turf scenario was used in the USEPA ecological risk assessment to represent paraquat maximum annual use rate, which was based on General Noncrop uses with maximum single application rate of 1.01 lb PQ+/A and a maximum of 10 applications per year (10.1 PQ+/A/year). Syngenta is amending the General Noncrop use pattern on the current Gramoxone SL 3.0 label to reduce the maximum general non-crop uses to a maximum of 6 applications/year at a maximum application rate of 1 lb PQ+/A with a minimum of a 7-day retreatment interval for a total of 6 lb PQ+/A/year.

EPA Response: The Agency appreciates the suggested refinements. Concerning the 'utilization of Kd value associated with soil type use in crop scenario' issue, there is no policy that prevents such a refinement, however, the Agency guidance on Tier 2 assessments though (*i.e.*, the assessment that occurs before any refinements are made), specifies that a single (mean) Kd or Koc value is used across all scenarios. Concerning sediment burial, the Agency provided a screening level risk assessment for benthic invertebrates using exposure calculations with sediment burial in the PRA to provide some characterization for the without sediment burial exposure values (historically, the Agency has not typically considered sediment burial in screening level assessments). Currently there is no guidance on when or how the sediment burial option should be used in risk assessment. If the Agency requires further refinement or additional characterization, the comments provided could be considered as potential further refinements in future assessments.

EPA-HQ-OPP-2011-0855-0128	EPA Statement
Section 8.1.2 Page 44	Monitoring The water samples (from NWIS, STEWARDS, STORET) comprise 1381 results from 64 sites. Among the 1381 water samples, there are only 14 detections by two organizations: California State Water Resources Control Board (CASWRCB) and South Florida Water Management District (SFWMD).

10. **Syngenta Comment (p. 44 of PRA):** Available surface water monitoring data indicate that paraquat is unlikely to be frequently detected as the detection rate is only 1.01% (14/1381). These findings are consistent with Syngenta's submitted targeted water monitoring studies for paraquat (Peters 2007a, Peters 2007b), which demonstrated extremely low detection frequency of paraquat residues; paraquat was detected in one raw water sample. The first of these studies (Peters, 2007a) monitored for paraquat residues in rural communities purposely selected to focus on areas of high paraquat usage. Over the course of 2-year monitoring period, a total of 1,192 raw water samples were collected and analyzed using immunoassay methodology for the presence of paraquat in a dissolved or bioavailable form. There were no quantifiable detections of paraquat at or above the LOQ of the analytical method, 0.10 ppb.

    The second monitoring study (Peters, 2007b) was conducted in urban environments. The sites monitored in this study targeted areas with potential paraquat exposure in surface water systems. Over the course of the 2-year monitoring period, water samples were collected at 21 scheduled intervals annually. A total of 1,056 raw water samples were analyzed for the presence of paraquat using immunoassay methodology; with the exception of one raw water sample (with a residue of 0.252 ppb), there were no quantifiable residues at or above the LOQ (0.10 ppb).

    EPA Response: The Agency appreciates the monitoring data summaries and references and will potentially consider them in future assessments.

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Page 44	Of the 1277 SWFMD samples, only 1 sample had paraquat detected at 1.4 µg/L. However, there is no indication of what type of water sample was collected (total, dissolved fraction, etc.) for any of the SWFMD samples. The other paraquat detections are all from CASWRCB with 13 detections (ranging from 0.24 to 3.6 µg/L) out of 68 water samples collected by this organization. These samples are total water samples indicating that the samples were not filtered and therefore, the paraquat detected may be attached to suspended sediment rather than dissolved in water (i.e., total samples are less indicative that the paraquat detected is bioavailable).

11. **Syngenta Comment (p. 44 of PRA):** Syngenta notes that these values likely represent a conservative estimate of exposure, especially since most samples did not include detectable levels of paraquat.

EPA Response: The Agency agrees that paraquat residues would be expected to be rarely found in non-targeted monitoring data sets. However, it is difficult to interpret what this means in terms of aquatic exposure. For example, it could mean that paraquat rarely reaches waterbodies or that any paraquat that does reach waterbodies is quickly adsorbed to suspended and bottom sediment between any periodic samplings that might occur in that waterbody. In both cases, it would be rare to observe paraquat in nontargeted monitoring data.

EPA-HQ-OPP-2011-0855-0128	EPA Statement
Section 8.2.2 Pages 50-51	Aquatic Invertebrates Table 8-1. Table 8-9. Aquatic Benthic Invertebrate Risk Quotients for Non-listed Species based on a 1.0 lb ai/A Application Rate Based on the available data, the risk to aquatic invertebrates from the use of paraquat is expected to be low from water column exposure, but potentially of concern over time from sediment exposure due to paraquat's persistence when adsorbed to sediment.

12. **Syngenta Comment (p. 50-51 of PRA):** The estimated risk to aquatic benthic invertebrates described in the USEPA ecological risk assessment for paraquat is markedly reduced if the aforementioned exposure refinements are applied. Updated RQs based on these refinements are provided in Table 8:

Table 8. Risk quotient (RQ) comparison for aquatic benthic invertebrates after exposure refinement.

Scenario	Application type	Sediment burial	Matrix	Target	RQ - EFED	RQ - Syngenta
MS Cotton	Aerial	Without	Pore water	Chironomus	0.71	0.06
MS Cotton	Aerial	With	Pore water	Chironomus	0.03	0.01
FL Turf	Ground	Without	Pore water	Chironomus	0.22	0.44
FL Turf	Ground	With	Pore water	Chironomus	0.22	0.44
MS Cotton	Aerial	Without	Sediment	Hyalella	5.00	2.85
MS Cotton	Aerial	With	Sediment	Hyalella	0.24	0.64
FL Turf	Ground	Without	Sediment	Hyalella	1.54	0.77
FL Turf	Ground	With	Sediment	Hyalella	1.54	0.77
MS Cotton	Aerial	Without	Sediment	Chironomus	1.67	0.95
MS Cotton	Aerial	With	Sediment	Chironomus	0.08	0.21
FL Turf	Ground	Without	Sediment	Chironomus	0.51	0.26
FL Turf	Ground	With	Sediment	Chironomus	0.51	0.26
MS Cotton	Aerial	Without	Sediment	Leptocheirus	1.52	0.86
MS Cotton	Aerial	With	Sediment	Leptocheirus	0.07	0.19
FL Turf	Ground	Without	Sediment	Leptocheirus	0.47	0.23
FL Turf	Ground	With	Sediment	Leptocheirus	0.47	0.23

EPA Response: The Agency appreciates the additional information/characterization submitted and if the Agency requires further refinement or additional characterization, the comments provided could be considered as potential further refinements.

EPA-HQ-OPP-2011-0855-0128	EPA Statement
Section 8.2.3 Page 52 Page 53	Aquatic Plants Risk estimates showed LOC exceedances (RQs of 4-26) to non-vascular aquatic plants (algae) from all registered uses of paraquat and all application rates. The weight of evidence shows that aquatic plants can be affected by paraquat exposure, but the amount of bioavailable paraquat to which they are exposed is difficult to predict. As previously discussed, paraquat's strong adsorption to particles or sediment, likely reduces its bioavailability to aquatic plants. The presence of dissolved or particulate matter may also influence the amount of paraquat that reaches aquatic plant tissue.

13. **Syngenta Comment (p. 52-53 of PRA):** Evaluation of which endpoint from aquatic non-vascular plants studies is most appropriate for ecological risk assessment is needed. While algal studies may consider multiple endpoints, growth rates are considered more robust than endpoints based on standing crop (cell density and biomass) for a given time-point since growth rate is independent of exposure time (USEPA 2012). For aquatic plants, study duration, conditions of temperature, light, and nutrients, and reported endpoints can vary considerably among studies. Furthermore, other resource limiting factors, such as nutrient depletion and self-shading, can confound the interpretation of reported plant ECxs. These factors may even affect study results, which could result in misleading estimates in certain cases for some species (US EPA 2012). Using absolute biomass can potentially result in particularly misleading ECx values when growth rates are modest, and a departure from exponential growth will be most pronounced in the treatments with the highest growth rates (USEPA 2012). With respect to toxicity testing, differences in design of the study can result in complicated growth dynamics and relationships that are difficult to interpret and apply (USEPA 2012). Moreover, as indicated by Bergtold and Dohmen (2011), the Organization for Economic Cooperation and Development (OECD) indicates a clear preference for growth rate as the appropriate endpoint in the lemna and algal toxicity test guideline (OECD 2011). Specifically, in the recommended OECD guideline for testing growth inhibition in freshwater algae and cyanobacteria (OECD, 2011), it states:

    "ECx values based upon average specific growth rate (ErCx) will generally be higher than results based upon yield (EyCx) if the test conditions of this Guideline are adhered to, due to the mathematical basis of the respective approaches. This should not be interpreted as a difference in sensitivity between the two response variables, simply that the values are different mathematically. The concept of average specific growth rate is based on the general exponential growth pattern of algae in non-limited cultures, where toxicity is estimated on the basis of the effects on the growth rate, without being dependent on the absolute level of the specific growth rate of the control, slope of the concentration-response curve or on test duration. In contrast, results based upon the yield response variable are dependent upon all these other variables. [Yield] is dependent on the specific growth rate of the algal species used in each test and on the maximum specific growth rate that can vary between species and even different algal strains. This response variable should not be used for comparing the sensitivity to toxicants among algal species or even different strains."

Therefore, relative growth rate was considered the most appropriate aquatic plant endpoint for evaluating potential effects on an aquatic plant community. The selected non-vascular plant endpoint (MRID 42601006) was based on cell density in *Navicula pelliculosa*, with an EC/IC50 = 0.4 µg PQ+/L. While an EC/IC50 value was not determined for growth rate, we note that the NOEC/LOEC for growth rate was 0.46/0.93 µg PQ+/L, whereas the NOEC/LOEC for cell density was 0.16/0.33 µg PQ+/L. Additionally, there is experimental evidence that paraquat's strong adsorption to suspended particles or sediment affects its bioavailability to aquatic plants. A similar assay (MRID 48877202) with *Navicula pelliculosa* was run in the presence of sediment, which returned an EC/IC50 > 623 µg PQ+/L, NOEC = 188 µg PQ+/L, and LOEC = 623 µg PQ+/L based on growth rate. Combined, these data indicate that sediment affects the bioavailability of paraquat to aquatic plants. The endpoints without sediment likely present a highly conservative estimate of hazard for non-vascular aquatic plants. A comparison of algal endpoints for *Navicula pelliculosa* is provided in Table 9.

Table 9. Endpoint comparison in *Navicula pelliculosa* studies.

Species	MRID	Endpoint	Sediment	EC/IC50	NOEC	LOEC
Navicula pelliculosa	42601006	Cell density	N	0.4 µg PQ+/L	0.16 µg PQ+/L	0.33 µg PQ+/L
Navicula pelliculosa	42601006	Growth rate	N	NA	0.46 µg PQ+/L	0.93 µg PQ+/L
Navicula pelliculosa	48877202	Growth rate	Y	> 623 µg PQ+/L	188 µg PQ+/L	623 µg PQ+/L

Considering exposure refinement, an updated list of RQs is provided in Table 10. Although more appropriate endpoints were examined, the only available EC/IC50 value was for cell density and was therefore used to calculate RQs.

Table 10. Risk quotients for non-vascular plants after exposure refinement.

Application rate (lb PQ+/A)	Application type	Spray drift fraction	Peak exposure (µg PQ+/L)	EC/IC50 (µg PQ+/L)	RQ
0.19	Ground	0.01	0.12	0.40	0.30
0.19	Aerial	0.04	0.40	0.40	1.00
0.25	Ground	0.01	0.15	0.40	0.38
0.25	Aerial	0.04	0.53	0.40	1.33
1	Ground	0.01	0.62	0.40	1.55
1	Aerial	0.04	2.13	0.40	5.33

Additionally, the SSD developed for non-vascular plants offers a higher-tier approach to assess risk. The refined surface water peak EECs for ground and aerial applications (Table 7) were compared to the SSD in Figure 5. These peak EECs are based on the highest maximum single application rate (1.0 lb PQ+/A) from the most recent paraquat label (Gramoxone 3LB) and thus represent a conservative estimate of exposure. Specifically, the acute (peak) exposure concentrations were 2.13 and 0.62 µg PQ+/L for aerial and ground applications, respectively. Still, these concentrations are expected to affect less than 10% of non-vascular plant species, suggesting *de minimus* risk at the community level due to functional redundancy and/or compensation.

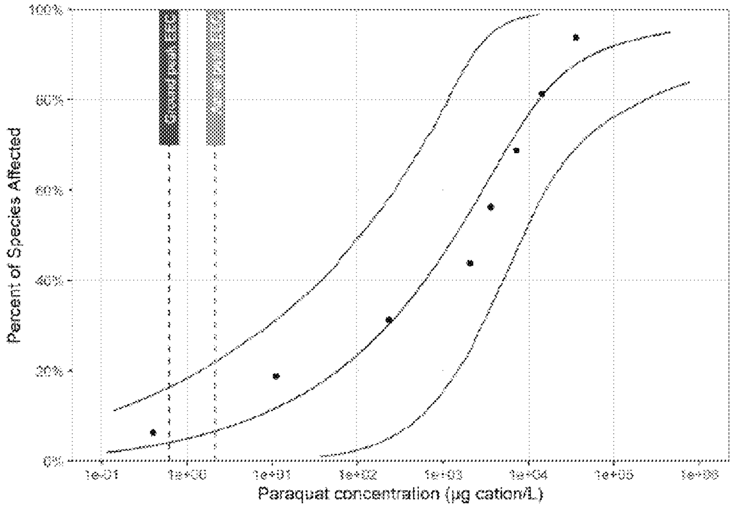

Figure 5. Species sensitivity distribution for non-vascular plants exposed to paraquat compared to peak exposure estimates.

<u>EPA Response</u>: As mentioned above in response to item #5, the selection of an endpoint with which to describe the potential risk from exposure to paraquat is a matter of science policy. The biomass diatom (cell density) endpoint used is consistent with current guidelines (850.4500). Information regarding endpoint refinement and SSDs can help characterize risk and/or risk management decisions.

EPA-HQ-OPP-2011-0855-0128	EPA Statement
Section 9.2 Page 57	Terrestrial Vertebrate Risk Characterization For acute dose-based exposure for birds and mammals, RQ values range from 0.01 to 57 (Table 9-2 and Table 9-3, also see Appendix D). For birds, RQs exceed the LOC for most feeding groups of non-listed birds for all uses, with the exception that for granivores, only the smallest size class have LOC exceedances, and only with multiple applications with a 7-day re-application interval. For mammals, acute RQs exceed the LOC for groups of non-listed mammals feeding on grasses, broadleaf plants and arthropods for all uses. Considering specifically a single application at the most common maximum application rate for most agricultural and non-agricultural uses (1.01 lb cation/A), most feeding groups of birds have exceedances, but only mammals feeding on grasses and broadleaf plants exceed the LOC. For the lower single application rate of 0.5 lb cation/A, only birds feeding on grasses, broadleaf plants, and arthropods had exceedances, and only the smallest size class of mammals feeding on short grasses had exceedances.
Page 66	For acute dietary-based exposures for birds, RQs range from 0.01 to 2.0 (Table 9-2) based on upper bound values. For all uses, birds feeding on short grass had exceedances; for multiple applications modeled using a 7-day re-application interval (premises/areas and multiple agricultural and non-agricultural uses), birds feeding on grasses, broadleaf plants, and arthropods also had LOC exceedances. For chronic exposures for mammals, dietary-based RQs (Table 9-4) were based on no measurable effects in rat reproductive or offspring body weight at the highest treatment level tested (7.5 mg cation/kg-bw, 108 kg cation/kg-diet, MRID 43685001). For mammals, the chronic risk was less certain with RQs as high as 81, based on a no-effect level from a rat 3-generation study. However, an additional line-of-evidence was used by estimating risk using rat prenatal growth data, which showed LOC exceedances for all uses. Chronic risk to mammals was identified for all uses, with the exception of some feeding groups from a single application.

Syngenta Comment (p. 57-66 of PRA): Syngenta posits that endpoints generated from studies more closely representing potential real-world exposure should receive greater weight in quantitative ecological risk assessment. Specifically, because the T-REX model assumes a dietary route of exposure, risk should be characterized based on dietary endpoints/calculations. Paraquat is also readily adsorbed to soil and foliar materials, and therefore dietary studies provide a more realistic estimate of paraquat bioavailability from food items compared to other routes of exposure (e.g., gavage). For acute risk to birds, reptiles, and terrestrial-phase amphibians (Table 9-2), the acute dietary-based RQs should receive greater weight in quantitative ecological risk assessment than the dose-based RQs. Similarly, the 3-generation dietary rat study provides a better estimate of mammalian hazard than the prenatal gavage study because the dietary route of exposure reflects that of the T-REX model, and because the dietary study considers the bioavailability of paraquat from food items. Thus, dietary endpoints/calculations should receive greater weight in the mammalian risk assessment. For the overall labelled uses of paraquat supported by Syngenta, the highest allowed single maximum application rate is 1 lb PQ+/A. For many use patterns, multiple applications are allowed. The highest overall yearly use is for preplant/preemergence or post directed applications for ginger with a total of 6 applications allowed at 1 lb PQ+/A for a total of 6 lb PQ+/A/year. It should be noted that the current label also allows up to 10 applications at 1 lb PQ+/A for general non-crop uses however Syngenta will be submitting an amendment to reduce this use pattern to a maximum of 6 applications per year

EPA Response: As mentioned above, the selection of endpoints with which to describe the potential risk from exposure to paraquat is a matter of science policy. Both dietary and dose-based endpoints are consistent with current guidelines and there are limitations to each approach. As noted in the T-REX model, the use of dietary study endpoints assumes that animals in the field are consuming food at a rate similar to that of confined laboratory animals. Energy content in food items differs between the field and the laboratory as does the energy requirements of wild and captive animals. The use of dose-based studies assumes that the uptake and absorption kinetics of a gavage study approximate the absorption associated with update from a dietary matrix, which, as noted in the comment, may not be the case for paraquat.

Section 9.2	Terrestrial Vertebrate Risk Characterization
Page 64 Page 65	Although the above analysis shows that multiple applications of paraquat are likely to exceed the mallard LOAEC by up to 14X, some uncertainty is acknowledged over whether chronic risk would be likely due to rapid plant death. For animals feeding on living plants, rapid plant death from paraquat exposure may make plants unpalatable and so chronic exposure may be unlikely. This uncertainty is limited to plant-eaters and would not apply to consumers of fruits, grains, seeds, or arthropods. A further point to consider in characterizing chronic dietary risk to terrestrial vertebrates is whether the food items sprayed with paraquat would be palatable on a chronic exposure basis. Because paraquat is a desiccant, animals consuming grasses and broadleaf plants might be more at risk from acute exposure than chronic exposure because the palatability of the plants would likely decrease as the plant food items desiccate. However, the desiccating action is not sufficiently rapid to eliminate the exposure pathway. Rapid wilting and desiccation begin within hours of application in full sunlight when paraquat produces superoxide radicals that disrupt the plasma membrane and the cell contents leak out. The leaves go from soft and turgid to dry and desiccated in a matter of days, with complete foliar necrosis occurring in 1 to 3 days and, for some plant species, leaves fall off in the final stages (2014, Shaner; BEAD, personal communication).

14. **Syngenta Comment (p. 64-65 of PRA):** Paraquat application leads to rapid foliar necrosis. Figure 6 below depicts this action, occurring within hours. A time lapse video of the onset to foliar necrosis is available at the Ohio State University Weed Science extension:

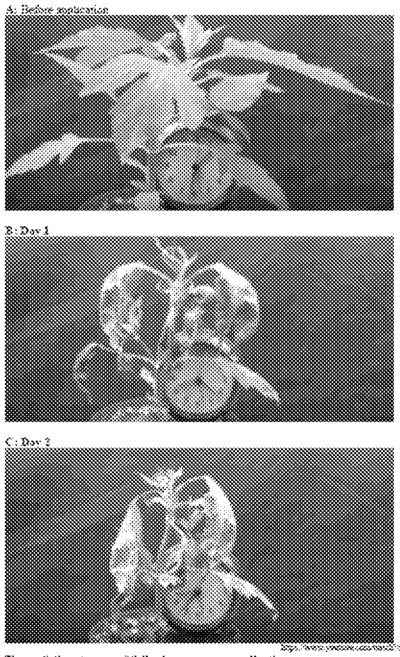

Figure 8. Giant ragweed following paraquat application.

As mentioned by EPA, this rapid action would reduce the palatability/availability of foliar dietary items to only a few hours following paraquat application. Therefore, chronic exposure from foliar dietary items is not expected for terrestrial vertebrates.

EPA Response: This information is noted and may be useful to enhance the terrestrial vertebrate risk characterization information discussed in Section 9.2 of the assessment. However, while palatability is likely to be quickly reduced following paraquat application, one unknown factor that is also considered is whether some vertebrates may actually consume more of the desiccated plants because of their reduced mass. This may conceivably occur when other plant options are not available. Therefore while this information is useful for discussion, the Agency supports its risk assessment approach and conclusions.

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Page 64	In two non-guideline studies, a formulated product containing paraquat dichloride was sprayed onto the eggs of pheasant (MRID 43942605) and mallard ducks (MRID 43942604). In the pheasant study, a decrease in the number of eggs hatched and the number of 28-d old survivors was observed at 1.0 lb cation/A, resulting in a study NOAEC of 0.5 lb cation/A. In the mallard study, an application rate of 2.0 lb cation/A increased the number of embryonic deaths (at days 13 and 19) as well as the number of dead embryos in the shell at day 31. At this concentration, the number of hatchlings and number of chicks surviving to 28 d were also decreased. The resulting NOAEC was 1.0 lb cation/A. This suggests that application timing may be important in preventing reproduction effects to birds and other egg-laying animals, and likely also to live-bearing animals.

15. **Syngenta Comment (p. 64 of PRA):** Successful nesting in arable crops usually starts after the crop is established, when the newly emerging and rapidly growing crop provides cover and food. Under these conditions, bird eggs will be further protected from the full spray by crop interception. Most passerines and game birds select nest sites providing good camouflage and cover to hide them from

predators, using available vegetation. This vegetation will lead to interception of part of the sprayed dose, with the level of interception depending on the degree of weed cover. Interception through nest cover will be quite influential in further lowering the potential exposure. Paraquat use also supports no-till farming, which offers several benefits compared to alternative practices. In no-till farming, weeds are not controlled by plowing, so its success relies on the use of non-selective herbicides like paraquat. Herbicide use in an arable field or orchard is expected to be less destructive than cultivations, rolling, mowing, or other mechanical farm operations. For ground nesting birds, these activities may result in the disturbance of adults, or damage to potential nesting sites resulting in them being abandoned. In some cases, this may lead to the destruction of potential nesting sites, nests and eggs. By contrast, no-till farming with paraquat reduces these risks while offering additional benefits (https://paraquat.com/en/use/agronomy/no-tillfarming), including those for:

- Soil: Straw and other unharvested plant materials reduce erosion by wind and water. Organic matter accumulates to provide structure and nutrients.
- Water: Good structure allows better retention and drainage of excess.
- Biodiversity: Habitats for flora, fauna, and microorganisms on and in soil.
- Crop: Good environment for root growth and supply of nutrients. Better drought tolerance. Less susceptible to waterlogging.
- Energy: Reduces use of fuel.
- Climate: Reduced emissions from fewer farm operations. Carbon sequestration in organic matter.
- Farm economics: Lower costs in fuel and machinery, greater profitability.

EPA Response: This information is noted and while it may be useful to enhance the terrestrial vertebrate risk characterization information discussed in Section 9.2 of the assessment, the Agency still supports the conclusions from the approach used. While paraquat toxicity may be a factor, reproductive effects for terrestrial vertebrates would vary by timing and opportunity for exposure. A reduction in nest disturbance from tilling is also a factor for consideration in risk characterization.

EPA-HQ-OPP-2011-0855-0128	EPA Statement
Section 9 Page 54-67	Terrestrial Vertebrates Risk Assessment T-REX modeling

16. **Syngenta Comment (p. 54-67 of PRA):** Potential risk to birds and mammals from foliar applications was identified in the preliminary ecological risk assessment for paraquat. However, these conclusions were based on highly conservative assumptions built into the T-REX model and use of the default 35-d foliar DT50 value. The assumption in T-REX that an organism will feed exclusively on a single food item from a single field beginning immediately after pesticide application is hyper-conservative particularly for chronic exposure as nearly all wildlife species in agro-ecosystems tend to forage in edge habitats rather than in treated fields (e.g., Best et al., 1990, 1995). No quantitative consideration is given to the diversity of diet, foraging behavior, or natural movement and migration of the organism of interest. Moreover, for single and multiple applications the model assumes a continual exposure to the instantaneous maximum concentration (at the point of application or maximum cumulative application), irrespective of dissipation kinetics. This is overly conservative especially from a chronic exposure perspective where it is highly unlikely that a bird or mammal would feed on items with maximum residues over an extended period of time. A more refined and accurate approach would be to model declining concentrations over time, as would be expected to occur in the field (Moore et al., 2014). Consequently, the model estimates unrealistically high

exposures in addition to unrealistic dietary assumptions and foraging behavior. Higher-tier models (e.g., Moore et al., 2014; Moore et al. 2010a; Moore et al. 2010b) attempt to more accurately reflect these attributes and thus provide a more realistic estimate of exposure, and consequently risk.

For higher tier risk assessment, Syngenta believes that dose-based RQs and subsequent risk estimates due to ingestion of individual diet items should be refined to reflect realistic proportions of diet items in small and medium-sized mammal diets. Due to the physiology of small and medium organisms (specifically birds and mammals), diets are typically comprised of a variety of items, but typically the greatest proportions are comprised of diet items in which the extractable energy:unit weight ratio is high (e.g., seeds, nuts, and invertebrates). For EPA's screening level risk assessment for paraquat, small mammals were assumed to consume 100% short grass for the short grass diet scenario in the screening-level T-REX model. As previously emphasized, dose-based RQ's for the short grass scenario are likely not representative of exposure to most small and medium-sized mammals based on diet composition.

Thus, very few, if any, small mammals have a diet solely comprised of short grass or broadleaf vegetation. This is supported by language within the T-REX Manual: "The risk assessment includes numerous calculations of dietary exposure for multiple weight classes of animals. However, there are energetic considerations which suggest that some weight class/food item combinations are not likely to occur naturally. For example, there are not likely to be many 15 g mammals or 20 g birds that exclusively feed on vegetation". This suggestion is supported by published literature that describes diet composition in small mammals for three representative species for which data exist: California mouse (*Peromyscus californicus*), wood mouse (*Apodemus sylvaticus*), and bank vole (*Clethrionomys glareolus*).

The California mouse primarily consumes fruits, seeds and flowers of shrubs. Arthropods and fungi also make up a small percentage of the California mouse diet (Merritt, 1974; Meserve, 1976a,b). A quantitative description of the California mouse diet was reported by Merritt (1974) for 20 California mice foraging in northern California. The study reported volumetric percentages of various feed items of mice collected in two different sampling quadrants. These diet items were classed as seeds and nuts, berries, arthropods, leaves and herbaceous stems. Trace amounts were assumed 0.5% by volume. The percentages were then corrected to account for exclusion of other items found in the gut (e.g., small amounts of fur and unidentified material). The averages of the quadrants for each diet item were used in the exposure assessment, assuming equivalent densities of diet items. The following proportions of diet items were assumed in the diet of California mouse by wet weight: 52% seeds and nuts, 25% leaves and herbaceous stems, 12% arthropods, 6.9% berries, and 4.1% fungi.

The wood mouse is an opportunistic feeder, taking mainly seeds and invertebrates. Jensen (1993) found that seeds of wheat, barley and oil-seed rape were among the five most preferred diet items for wood mice. Pelz (1989) studied arable dwelling wood mice in a three year crop rotation system with sugar beet, winter wheat and winter barley in an agroecosystem within Europe. The study examined diet proportions for each month between March and November and wood mice diets were dominated by cereal grains, dicotyledon seeds, and insect larvae, while vegetative plant tissue comprised <25% of diets for all months studied except November (Pelz 1989). Pelz (1989) also reported that when crop seeds were not available, wood mice relied on wild plant seeds. Additional studies indicated that the principal diet of wood mouse throughout the year consisted of >40% seeds/cereal grains (and up to 73% for some habitats), followed by animal matter, and small amounts of vegetative plant tissue (Hansson 1985, Canova 1993). In addition, Barber et al. (2003) reported that 90% of trapped wood mice contained seeds in their diet.

Bank voles (*Clethrionomys glareolus*) also have a diverse diet consisting of leaves, stems, seeds, berries, roots, bark, fungi, and animal-based items (Canova 1993, Abt and Bock 1998). They typically have <50% of their diet composed of leafy vegetative items. In a mixed European farmland ecosystem, bank voles primarily consumed berries and fungi and then during mid-winter their diets seasonally shifted to grasses (Abt and Bock, 1998).

In summary, Syngenta suggests that risk estimates associated with dietary exposure to different diet items be refined to reflect ecologically-likely proportions for small and medium-sized mammals. This would mean that overall risk estimates are driven by RQs associated with diet items likely to have the greatest proportion within the diet. For small and medium-sized mammals this would be seeds and invertebrates, which have chronic RQs that do not exceed LOCs. The least weight should be given to short grasses, which have the greatest RQs in the current paraquat risk assessment, due to their limited occurrence in small mammal diets.

EPA Response: This information is noted and may be useful for discussion regarding the other terrestrial vertebrate risk characterization information discussed in Section 9.2 of the assessment, and the Agency does acknowledge that there are some weight class/food item combinations that are not likely to occur naturally as cited in the T-REX manual. However, the Agency supports its approach and conclusions.

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Page 70	Based on acute oral toxicity, six out of eight castes of adult bees had LOC exceedances at the highest single application rate (1.5 lb cation/A) for alfalfa and clover (Table 10-3, also see Appendix D).

17. **Syngenta Comment (p. 70 of PRA):** The 1.5 lb PQ+/A single application rate that resulted in the modelled exceedances is not supported on Syngenta's paraquat labels. Syngenta supports a single maximum application rate of 1 lb PQ+/A.

    EPA Response: Registration Review assessments are done for all uses/labels that are registered at the time of the assessment and notes that Syngenta does not support an application rate of 1.5 lbs/acre. Application rates of 0.5 and 1.01 lb cation/acre were also assessed.

EPA-HQ-OPP-2011-0855-0128	EPA Statement
Section 10 Page 67 Page 70 Page 74	Terrestrial Invertebrate Risk Assessment Because paraquat is used as a desiccant, the likelihood that it would be applied directly to crops during blooming periods seems low for most crops, but it is not unfathomable. For example, paraquat might be applied between rows of blooming fruit trees, which, though not directly on the crops, might be in close proximity. As mentioned in Section 10.1, although multiple crops for which paraquat is registered are attractive to pollinators, the use pattern does not suggest that paraquat would be applied directly to crops in blooming phase. Paraquat is used primarily as a burn down product before crops are planted in the spring (corn, cotton, soybeans, peanuts, etc.). Small winter and spring annual weeds (broadleaf and grass species) could be present and flowering when those applications are made and would be targeted by the paraquat application. If sprayed, those plants and their flowers would likely show symptoms within a few hours and be dead within 1 to 3 days. Paraquat is also used as a desiccant just prior to harvest on crops like potato to get rid of the vines. In those cases, there may be some large flowering plants in the field where pollinator exposure could occur. If the plant is large enough, some flowers might escape direct contact with paraquat and survive for a few more days until the whole plant wilts and dies. In that case, pollinators would not be expected to be exposed (BEAD, personal communication[6]). If applied between rows while crops are blooming, however, this would potentially be a route of exposure for pollinators. With the locosystemic nature of paraquat, the potential may exist for its presence in parts of plants that may be consumed. Due to rapid plant death, it seems unlikely that it would be taken up by the target plant and transported to pollen; it would more likely only be available in off-field non-target plants or pollen as a result of spray drift.

18. **Syngenta Comment (p. 67-74 of PRA):** It is unlikely that pollinators would be exposed during blooming periods due to application timing. As mentioned previously, due to the rapid desiccating action of paraquat, it is unlikely that pollinators would be exposed to pollen on a chronic basis.

    EPA Response: The Agency agrees that application timing and desiccation effects are likely factors in pollinator exposure, as discussed in **Section 10** of the assessment. Risk to pollinators could not be fully assessed due to lack of chronic toxicity data for adults and both acute and chronic data for larvae.

EPA-HQ-OPP-2011-0855-0128	EPA Statement
Page 74	Table 10-4. AgDrift Tier 1 distances to remove the presumption of oral risk to adult nectar forager and worker honeybees

19. **Syngenta Comment (p. 74 of PRA):** The maximum single application rate supported by Syngenta for paraquat is 1.0 lb PQ+/A. The 1.5 lb PQ+/A application rate is not supported on Syngenta paraquat labels. Syngenta is amending ground spray drift mitigation on the current Gramoxone 3LB label to require spray nozzles that will produce ASABE S572.2 coarse or larger spray quality for all applications. For labels with these restrictions, estimated distances related to fine droplet size are no longer relevant and do not reflect the potential risk associated with use of these products.

    Additionally, Gramoxone SL 3.0 provides aerial spray drift mitigation by specifying maximum boom height of 10 ft, maximum boom length 65% of the wingspan for airplanes or 75% of the rotor blade diameter for helicopters, 50% swath displacement and maximum wind speed of 10 mph. Syngenta recalculated distances for aerial spray presented in Table 10-4 based on these specific label mitigation using Tier II AgDRIFT (version 2.1.1). For all aircraft simulated (Air tractor AT-401, Ag Husky, Wasp helicopter, Air tractor AT-502), Tier II AgDRIFT generated no distance (0 ft) is required for single application rate of 1.0 lb PQ+/A or lower to remove the presumption of oral risk to adult nectar forager and worker honey bees. Syngenta supports the use of Tier II AgDRIFT results in risk assessment to reflect label specific mitigation.

    EPA Response: Registration Review assessments are done for all uses/labels that are registered at the time of the assessment. The Agency notes that Syngenta does not support an application rate of 1.5 lbs/acre. Application rates of 0.5 and 1.01 lb cation/acre were also assessed. The AgDRIFT model is approved for use in the Agency's risk assessments and is applied to bees following the same procedures as for other assessed taxa. This is consistent with the Agency's response to comments regarding pollinator off-field risk estimation for other chemicals, such as neonicitonoids, see p. 9 of the response to comments document (dated January 6, 2020, DP 447635), available in the clothianidin docket: (https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0865-1170). Further refinements can be done as needed.

EPA-HQ-OPP-2011-0855-0128	EPA statement
Section 10.3.2 Tier I Risk Estimation (Oral Exposure); Off-Field Risk; p. 72	**Off-Field Risk** In addition to bees foraging on the treated field, bees may also be foraging in fields adjacent to the treated fields. AgDrift analysis showed that distances needed to remove the presumption of risk for the bee caste at highest risk (workers foraging for nectar) were: • 4 to 46 feet for the highest application rate (1.5 lb cation/A) for alfalfa and clover; • 4 to 20 feet at the highest application rate for most uses (1.01 lb cation/A); and • <1 to 7 feet at the lowest application rate for most uses (0.5 lb cation/A).

The maximum single application rate supported on Syngenta paraquat labels is 1.0 lb PQ+/A. The 1.5 lb PQ+/A application rate and fine droplet spray quality are not supported by Gramoxone 3LB label. Furthermore, Syngenta is amending ground spray drift mitigation on the current Gramoxone 3LB label to require spray nozzles that will produce ASABE S572.2 coarse or larger spray quality for all applications. The 1.5 lb PQ+/A application rate and fine droplet are not supported by Gramoxone 3LB label, therefore, associated RQs and distances based upon these parameters are not relevant for this product and should be reevaluated with the product specific corresponding parameters. As described in the comment to Table 10-4 above, no distance (0 ft) needed to remove the presumption of risk from aerial application for single application rate of 1.0 lb PQ+/A or lower based on Tier II AgDRIFT (version 2.1.1). Off-field risk should be refined to include spray drift mitigation in the most recent label and the use of Tier II AgDRIFT results.

Off-Field Risk:
To assess the potential risk to bees exposed to potential paraquat drift in off-field habitat, EPA used the BeeREX model (v.1.0) to determine risk quotients (RQs) for acute contact and oral and chronic oral exposure routes based on foliar application rates. The level of concern (LOC), which is 0.4 for acute and 1.0 for chronic, divided by the RQ determined the drift fractions that would be acceptable such that the RQ was less than the LOC for acute and chronic exposure. The drift fraction was then used with the AgDRIFT® model (v. 2.1.1) to estimate the distance at which acceptable drift deposition would occur for ground and aerial applications. The distance required for the drift fraction to be low enough such that the RQ no longer exceeded the acute or chronic LOC for acute contact and oral as well as chronic oral scenarios was determined. It is important to note that this method was not a component of the bee risk assessment process that was vetted with the Scientific Advisory Panel (SAP) and is not part of the formal bee risk assessment guidance (US EPA, PMRA, CDPR 2014). Syngenta agrees with The Neonicotinoid Consortium comments concerning the off-field assessment method in determining risk to bees and can be considered relevant for other pesticide active ingredients where this method has been used in the risk assessment for pollinators including paraquat. Those comments (EPA-HQ-OPP-2011-0581-0068) are summarized as follows:

- Any spray buffers that might be recommended based on off-field assessments are not necessary based on current pollinator protection goals and given the fact that label language is already in place, for compounds that are acutely toxic to bees, that prohibits the drift to flowering crops and weeds. Thus, for acutely bee toxic pesticides, prior to and during application, measures need to be taken that will minimize any off-field exposure and potential risk to bees foraging in off-field field habitats.
- The off-field assessment method uses conservative default values as inputs to the AgDRIFT model which can be refined based on label specific language. Additional aspects that likely lead to overestimation of exposure are that the model assumes there is no interception by the crop canopy and that winds are unidirectional and constant to the off-field area.
- Off-field spray drift is predominantly composed of the smallest droplet sizes (driftable fines) that do not deposit on plant structures (i.e. leaves, stems, flowers) in the same fashion as a direct, saturating overspray due to the nature of atmospheric mechanisms impacting the dispersion of airborne particles and their interaction with solid surfaces.
- The proposed EPA method incorporates both contact and oral exposure routes over both acute and chronic exposure durations. From a dietary standpoint, the amount of drift that could potentially land on pollen and/or nectar is likely much lower compared to what could potentially land on leaf material. In addition, off field habitat immediately adjacent to a crop where a foliar application was made and the proportion of the habitat where spray drift actually deposited on the plants, taking into consideration plant interception, is likely small

and would represent a very small portion of the overall foraging range and insignificant proportion of the dietary needs of a honey bee colony. The chronic endpoint is also based on a continuous oral exposure even though degradation, based on available pollen and nectar residue studies (for other compounds like neonicotinoids), can be substantial.

• Given the number of overly conservative assumptions concerning both the route and duration of exposure for off-field drift to bees, the acute and chronic dietary component should be removed and, if any off-field assessment is needed, the focus should be on assessing the potential risk to bees from acute contact exposure to spray drift.

EPA Response: As discussed above in response to Comment 18, the Agency notes that Syngenta does not support an application rate of 1.5 lbs/acre, and lower application rates were also assessed. Also, as discussed above, the assessment followed the same procedures as for other assessments but can make future refinements as needed.

EPA-HQ-OPP-2011-0855-0128	EPA Statement
Page 75	Table 11-1. TerrPlant calculated EECs for terrestrial and semi-aquatic plants near paraquat terrestrial use areas

20. **Syngenta Comment (p. 75 of PRA):** The maximum single application rate presented in Table 11-1 is 1.5 lb PQ+/A which is greater than the 1.0 lb PQ+/A maximum application rate allowed on Syngenta paraquat product labels.

Syngenta recalculated distances for aerial spray based on aerial spray drift mitigation specified in the Gramoxone 3LB product label. Tier II AgDRIFT (version 2.1.1) was used with boom height of 10 ft, boom length of 75% for aircraft except helicopter (65%), droplet size distribution set to ASAE S572.2 coarse to very coarse, swath displacement fraction of 0.5 and wind speed of 10 mph. Tier II AgDRIFT generated no distance (0 ft) is required to remove the presumption of risk for all aircraft simulated (Air tractor AT- 401, Ag Husky, Wasp helicopter, Air tractor AT-502). Syngenta advocates for the use of Tier II AgDRIFT results in risk assessment to reflect label specific mitigation.

EPA Response: This information is noted and while the information is useful to enhance the terrestrial plant risk characterization information discussed in Section 11.2 of the assessment, the Agency supports the approach taken and conclusions found. As discussed above in response to Comment 18, the Agency notes that Syngenta does not support an application rate of 1.5 lbs/acre, and lower application rates were also assessed. The risk conclusions were the same for 0.5, 1.01, and 1.5 lb cation/acre. The AgDRIFT model was applied following the same procedures as for other assessed taxa and using the Tier I calculations, the distance to the fraction of applied to remove a presumption of risk was reduced from 10-17 feet at 1.5 lb cation/acre to 4-7 feet at 1.01 lb cation/acre and <1 foot at 0.5 lb cation/acre.

EPA-HQ-OPP-2011-0855-0128	EPA Statement
Page 75	Based on these endpoints and the EECs calculated using TerrPlant (Table 11-1), the LOCs are exceeded for non-target plants exposed to spray drift (based on vegetative vigor endpoints as described above) had exceedances for all application rates from aerial spray (RQs from 1.2-3.6) but not from ground spray (Table 11-2). Distances to remove the presumption of risk range from <1 foot to 17 feet, depending in part on droplet size.

21. **Syngenta Comment (p. 75):** Based on recalculated distances to remove the presumption of risk following specific aerial drift mitigation in the most recent label for paraquat (Gramoxone 3LB), no distance (0 ft) is required for aerial spray (see comment related to Table 11-1).

    EPA Response: As mentioned above in response to Comments #18 and #20, this information is noted and, while it is useful to enhance the terrestrial plant risk characterization information discussed in Section 11.2 of the assessment, the Agency supports the approach taken and conclusions made. Both the TerrPlant (v. 1.2.2) and AgDRIFT models were applied following current policies. Future refinements can be made as needed.

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Beyond Pesticides Comments on the PRA and EPA Responses:

1. **Beyond Pesticides Comments** on **Uncertainties and Data Gaps**
   The rat reproduction endpoint used for chronic risk estimation show no effects at the same dietary concentration causing reproduction effects to birds (mallard). That level was below estimated exposure levels so risk quotients for mammals have some uncertainty, and chronic risk cannot be precluded. Additional information, however, would not likely change the risk conclusions because the acute risk to mammals was determined to be high for all registered uses. Also, an additional line-of-evidence was investigated by using rat prenatal growth data to estimate risk, which also showed chronic risk above the LOC for all uses.

   Chronic toxicity of paraquat to freshwater crustacea is uncertain. In sub-chronic sediment toxicity studies, crustacea (freshwater amphipod), are more sensitive than insect larvae (midge); however, the midge was the only taxon for which chronic sediment toxicity data were available. Due to the persistence of paraquat, effects of long-term exposure of benthic organisms is largely unknown, especially via ingestion of sediment-bound paraquat. However, a chronic freshwater amphipod study would not likely provide sufficient information to change risk conclusions due to the difficulties in assessing exposure. Likewise, information from the open literature suggests that some crustacean, fish, and amphibian species may be more sensitive than the endpoints for which quantitatively usable toxicity data are available to support higher RQs.

   With its longevity, potential for paraquat presence in many places in the environment is not easily characterized. Several labels do not specify the re-application interval, so a 7-day interval was conservatively assumed for exposure estimates. There is little fate data available to characterize how paraquat behaves in the environment after soil or sediment adsorption sites become saturated. paraquat is likely to enter surface waters bound to soil particles as a result of erosion and run-off, and subsequently be redeposited onto the beds of surface water bodies or lowland areas that receive eroded sediments from uplands (e.g. riparian zones, wetlands).[10]

   A full risk assessment for terrestrial insects was not completed by the Agency. There are a few incidents reported in the literature where honey bees have been poisoned by paraquat. In one such incident during one dry spell of weather, paraquat spraying in a field in the UK resulted in small puddles to which bees were attracted and subsequently died.[11] Honey bees commonly seek water in such small puddles or saturated soil. Such exposure scenarios are not considered, which given paraquat's binding affinity to clay soils and longevity would indicate a serious risk to honey bees and especially mason bees and other pollinators which use clay particles in building their nests. The Agency did list several data gaps to be filled for honey bee tests to better document pollinator risk, including:
   - Honey bee adult acute oral toxicity
   - Honey bee larvae acute toxicity
   - Honey bee adult chronic oral toxicity
   - Honey bee larvae chronic toxicity
   - Semi-field testing for pollinators (tunnel or colony feeding studies)
   - Field trial of residues in pollen and nectar
   - OCSPP 850.3040 (Tier 3): Field testing for pollinators

   An additional route of exposure to birds that is not fully assessed would be the propensity of many bird species to ingest clay or other soil particles likely contaminated with paraquat. As already noted, paraquat readily and persistently binds to soil, especially clay particles. Birds ingesting clay particles as dietary grit or when attached to soil invertebrates, like earthworms, will result in higher exposure (acute and chronic) than considered in the avian RQ calculations. However, additional consideration of this added exposure would serve only to increase the magnitude of RQ exceedance of LOCs, which are already substantial.

The ecological risk assessment uses a fish early life stage (ELS) test to estimate chronic fish toxicity. This is incorrect. The fish ELS is a sub-chronic test of sensitive life stages. It does not adequately address potential adverse effects on reproduction or transfer of test chemical to eggs/offspring from parental exposure. Only a complete life-cycle test can satisfy the requirements of a chronic toxicity test. An early life-stage test cannot be appropriately substituted.[14,15,16] A full life cycle test (OSCPP 850.1500) or medaka extended one-generation test (OSCPP 890.2200) is needed to fulfill a requirement for reproduction and chronic toxicity.

Footnotes in section:
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[11] PAN UK. 2002. Bee poisoning link with paraquat. Pestic News 55:11. http:// www.pan-uk.org/pestnews/Issue/ pn55/pn55p11.htm.
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Additionally, the old pre-1998 reproduction toxicity test (OSCP 870.3800) should be replaced with one performed under the current guidelines or substituted with an EOGRT (OECD 443).
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EPA Response: The assessment was conducted in accordance with current policies and procedures. The comments made regarding the mammalian and avian conclusions tend to support the conclusions found. The commenter acknowledges difficulties in predicting fate of paraquat in sediments. The Agency acknowledges that the full suite of Tier 1 pollinator data are not available at the time of this assessment. The Agency agrees that a fish early life-stage (850.1400) study is not as complete as a fish full life-cycle (850.1500) chronic study in the endpoints measured. However, the endpoints assessed are believed to capture sensitive life stages and stands behind its use as a chronic toxicity screening tool.

Center for Biological Diversity Comments on the PRA and EPA Responses:

1. **CBD Comments** on **Incidents**:

   The Number of Ecological Incidents Reported are Substantial and Cause for Concern

   The EPA found a substantial number of damage incidents reported to the Agency that were compiled in the Incident Data System (IDS).20 This large amount of incident information should be taken as evidence that paraquat cannot be used in accordance with FIFRA.

   The reporting requirements for the IDS are ridiculously high:[21]

   - For fish, specific information on the pesticide causing the harm is not required unless 1,000 or more individuals of a schooling species or 50 or more individuals of a non-schooling species have been killed.
   - For birds, specific information on the pesticide causing the harm is not required unless 200 or more individuals of a flocking species, 50 or more individuals of a songbird species, or 5 or more individuals of a predatory species have been killed.
   - For mammals, reptiles and amphibians, specific information on the pesticide causing the harm is not required unless 50 or more individuals of a relatively common or herding species or 5 or more individuals of a rare or solitary species are killed.

   Any incidents resulting in harm that does not meet the above numerical thresholds are only required to contain the date of the incident and the number of individuals affected. Information on what pesticide caused the damage or even what taxa were affected are not required to be reported under a W-B incident.[22]

   Given that the EPA is completely hamstrung by these ineffective reporting requirements and that reported incidents are very under-representative of harm that has occurred, the sheer number of incidents in the IDS system indicate that paraquat is responsible for widespread environmental damage.

   EPA Response: Under FIFRA EPA is required to consider both the risks and benefits associated when making decisions regarding the continued registration of pesticides. The Agency acknowledges incidents associated with paraquat use and these were discussed in the assessment. They can be used as one line of evidence when considering potential risk to non-target species, as they can provide real-world support that exposure routes are complete, however they are only one component of risk assessment. In addition, the Agency also considers benefits associated with the use of paraquat.

2. **CBD Comments** on **Data Gaps**:

   The EPA Must Require that the Registrant Provide All Necessary Data and Studies

   The EPA must have substantial evidence to re-register this pesticide. To do so, the EPA must require all necessary data and studies, including, but not limited to any previously identified data or study gaps, additional studies to evaluate effects on pollinators in accordance with the *Guidance for Assessing Pesticide Risks to Bees,*[23] information concerning estrogen or other endocrine disruption effects,[24] and <u>any</u> information that this pesticide or products containing this pesticide may have synergistic effects.

   This is information that the EPA must require from the applicant in the first instance pursuant to 40 C.F.R. § 159.195(a), which require registrants to submit information that they reasonably should know that EPA might regard as raising concerns about the appropriate terms and conditions of registration of a product. The applicant may have information regarding synergy, whether in a U.S. Patent Application or as a result of its research and development. Failure to require any of the above information will result in the EPA underestimating adverse effects and lacking substantial evidence to support registration.

EPA Response: Data gaps, chiefly for pollinators, are acknowledged. The timing for Registration Review did not allow for all the pollinator data to be acquired and included in all the assessments. The EPA is currently developing a policy on how to consider claims of synergy being made by registrants in their patents. On September 9, 2019, the EPA released an interim process for public comment, available at regulations.gov in docket EPA-HQ-OPP-2017-0433. After the agency has received and considered public comment on the proposed policy, and once that policy has been finalized, the EPA will consider its implications on the EPA's final decision for paraquat.

City of Sacramento Department of Utilities Comments on the PRA:

1. **City of Sacramento Comments** on **Drinking Water Assessments**:
With this letter we are specifically commenting on the revised Human Health Risk Assessment (HHRA), "Paraquat Dichloride: Draft Human Health Risk Assessment in Support of Registration Review" (June 26, 2019; EPA-HQ-OPP-2011-0855-0121).

We appreciate that when EPA conducts its pesticide registration review risk assessments, the assessment considers the potential for the pesticide to affect drinking water quality. EPA's drinking water risk assessment, which addresses acute, chronic, and cancer risks (when relevant), typically uses both predictive modeling and an evaluation of monitoring data to estimate human exposures through drinking water. However, EPA does not appear to have used this standard approach in the assessment of drinking water and dietary exposure risks for Paraquat dichloride. The draft HHRA includes neither a review and summary of surface water monitoring data for paraquat dichloride, nor water quality modeling to predict environmental concentrations according to current EPA protocols.

Paraquat dichloride is widely used in the Sacramento River watershed upstream of our municipal water intakes, on a variety of crops including tomatoes and other row crops, tree nuts, and rice. Based on its high annual usage throughout the Sacramento River watershed, Paraquat is a pesticide of concern for our drinking water supplies. Although not specifically called for in the Final Work Plan ("Paraquat Dichloride Final Work Plan, Registration Review", May 2012; EPA-HQ-OPP-2011-0855-0011), the Scoping Document ("Paraquat Dichloride (Paraquat) - Human Health Risk Scoping Document in Support of Registration Review",12-06-2011; EPA-HQ-OPP-2011-0855- 0004) clearly indicates that the drinking water assessment will be updated with current modeling protocols:

> "In order to bring the drinking water assessment up to date with current data, simulation models and guidance, a new drinking water exposure assessment will be conducted to support future human health dietary risk assessments of paraquat. The drinking water assessment will incorporate model estimates of paraquat in surface water and ground water. Concentrations of paraquat in surface waters will be estimated using PRZM/EXAMS (see description above) with Index Reservoir as the receiving water body." (Scoping Document, p. 5)

However, rather than relying upon EPA's standard surface water modeling approach to develop an estimated drinking water concentration (EDWC), EPA's Environmental Fate and Effects Division (EFED) derived the EDWC based on a review of a non-guideline supplemental mobility study (MRID-4865950), which involved a limited number of jar tests to estimate the effectiveness of conventional drinking water treatment in removing Paraquat dichloride from raw water samples spiked at 30 ppb, The mobility study, which is not included in the Paraquat dichloride registration review docket, was reviewed in a 2012 USEPA EFED memorandum ("Paraquat Dichloride - Review of Jar Test Results for Drinking Water Assessment Purpose", Jan. 10, 2012; EPA-HQ-OPP-2011-0855- 0129). The drinking water exposure estimate was not otherwise refined for the current draft HHRA.

The lack of modeling and reliance on a review of the jar tests/mobility study to establish the EDWC is problematic. The presence of pesticides in the source water may cause risk to human health and welfare, and may necessitate a targeted process in drinking water treatment. Targeted treatment of surface water supplies to remove complex organic compounds typically requires advanced treatment technologies, such as membrane filtration or activated carbon filtration, which are not universally implemented in drinking water treatment and are expensive to install, operate and maintain. Mitigation at the point of pesticide use to prevent potential pollution of drinking water sources is preferable, to ensure that downstream users will not have to bear the burden of cleanup from controllable upstream pollutant sources, as well as to better protect public health. Protection of source waters is an essential aspect of the multi-barrier approach to water supply source protection endorsed by USEPA, the State of California Division of Drinking Water, and the American Water Works Association. The Multi-Barrier Approach is defined as "an integrated system of procedures, processes and tools that collectively prevent or reduce the contamination of drinking water from source to tap in order to reduce risks to public health". Source water protection is a critical component of the Multi-Barrier Approach.

Surface water modeling is certainly indicated in risk assessment for any pesticide for which there may be concerns regarding human health risks via the drinking water exposure route. Paraquat exposure is known to be associated with respiratory and neurological risks, including possibly Parkinson's disease. While the risks are normally attributed to occupational exposure, and the dietary (food and drinking water) exposure levels projected by EPA were determined to be within acceptable levels of risk for acute and chronic dietary exposure, the acute and chronic Population Adjusted Doses (aPAD and cPAD) are not negligible. From the 2019 draft HHRA (p. 9):

> "For the acute assessment...The most highly exposed population subgroup is Children 1-2 years old which utilizes 38% of the aPAD. The general U.S. population utilizes 20% of the aPAD. For the chronic assessment, the general U.S. population and all population subgroups have risk estimates that are below HED's level of concern (*i.e.*, 100% of the cPAD). The most highly exposed population subgroup is Children 1-2 years old which utilizes 25% of the cPAD. The general U.S. population utilizes 6.6% of the cPAD."

Additionally, the Ecological Risk Assessment ("Paraquat: Preliminary Ecological Risk Assessment for Registration Review", June 26, 2019; EPA-HQ-OPP-2011-0855-0128) does include surface water modeling using the recommended predictive models, with results for Expected Environmental Concentrations (EECs) for surface water ranging up to 10.5 ppb, which is roughly one third of the USEPA Health Advisory (Lifetime) for Paraquat dichloride of 30 ppb.

The 2019 Ecological Risk Assessment also includes a summary of surface water monitoring data, indicating that paraquat has been detected in California monitoring at levels up to 3.6 ppb. This level is within an order of magnitude of the USEPA Health Advisory (Lifetime) for Paraquat dichloride of 30 ppb.

Because of the known health risks of Paraquat dichloride, the large population in the lower Sacramento River watershed (and other urban areas) at risk of exposure through the dietary (food and drinking water) route, the lack of modeling to derive the EDWC used in the draft HHRA, and the absence of an inventory of applicable surface and groundwater monitoring data in the draft HHRA, it is apparent that a revised draft HHRA should be prepared, to include a Drinking Water Assessment incorporating current USEPA water quality modeling techniques.

We therefore request that EPA revise the draft Human Health Risk Assessment for Paraquat dichloride to include the following:

- Preparation of a Drinking Water Assessment to accurately and adequately characterize potential dietary exposure to Paraquat dichloride via the drinking water route.
- Revision of the EDWC based on EPA's standard surface water modeling approach, using EPA's current pesticides/surface water model: the Pesticide Water Calculator (PWC), running the Pesticide Root Zone Model (PRZM, v 5, November 15, 2006) and the Variable Volume Water Body Model (VVWM, 3/6/2014), or more current versions as updated by EPA.
- Refinement of the dietary (food and drinking water) exposure risks based on the revised EDWCs produced by surface water modeling as per above.
- Inclusion within the drinking water assessment of a summary of recent surface and groundwater monitoring data for Paraquat dichloride, as is standard in EPA's drinking water assessments.
- Reference to the USEPA Health Advisory (Lifetime) for Paraquat dichloride in the drinking water assessment and revised draft HHRA.

Because our drinking water supply intakes are downstream from an important agricultural region, and because multiple pesticides have been detected in the surface waters upstream of our intakes, we also have concerns about cumulative and potential synergistic effects of exposure to multiple pesticides. Specifically, we request that EPA, to the extent feasible, include the following additional considerations when evaluating human health risk from pesticides:

- Evaluate effects of the metabolites, degradates, and transformation products formed during and subsequent to water treatment processes.
- Evaluate effects of water treatment processes on residue removal and on the creation of transformation products from the parent chemical.
- Assess cumulative and possible synergistic effects of pesticides and their breakdown products in drinking water.
- Require water quality monitoring and data collection by pesticide registrants to support EPA's evaluation of the above.

EPA Response: The Agency discusses in the aquatic modeling section of the PRA (Section 8.1.1) that paraquat adsorbs very strongly and completely to any soil or sediment (suspended or bottom). It is this property of paraquat that prevented the Agency from using the Agency's standard exposure models to estimate aquatic exposure concentrations in the PRA. This same property of paraquat was also demonstrated in the results of the jar tests in MRID 48659501:

> *Based on jar test alone, the water samples from Illinois, Kentucky, and Texas show the remaining paraquat contents are at about or below the detectable limit of 0.15 ug/L. The water samples from Florida and North Carolina show the remaining paraquat level of about 8 to 10%, with additional filtration, the level of paraquat is reduced to about or below the detectable limit.*

The Data Evaluation Record (DER) concluded:

> *^{14}C-paraquat, spiked at ~30 ppb into the raw surface water samples from five representative US CWS (community water supply) facilities, was effectively removed by a combination of typical water treatment processes conducted on a laboratory-scale: the "laboratory jar test" (coagulation using alum with either lime or soda ash, flocculation and sedimentation), followed by duel media filtration (anthracite atop of filtering sand). The combination process was able to reduce the level of ^{14}C-paraquat to approximate or below the limit of detection of about 0.15 ug/L (ppb). The jar test results allow the Agency to better characterize potential levels in finished water for drinking water assessment purpose. The level of paraquat in the finish water of 0.15 µg/L should be used for the drinking water assessment.*

Therefore, the Agency relied on the jar test results for setting the EDWC and anticipates that any applied paraquat will be adsorbed tightly to soil particles either in the field to which it is applied or any natural waterbody to which it is transported (*i.e.*, via erosion or spray drift). Any paraquat attached to suspended sediment particles in the raw water at the water treatment plant would be removed during treatment. Because the analytical methods used in the jar test could not measure concentrations below the method detection limit of 0.15 µg/L, that detection limit was recommended as a conservative EDWC to be used in the human health risk assessment. The Agency acknowledges that there are some monitoring data that indicate paraquat detections at higher concentrations than the 0.15 µg/L as reported in the PRA, but believes that these monitored concentrations reflect paraquat adsorbed to soil particles suspended in these water samples, which would be removed during water treatment.

National Agricultural Aviation Association (NAAA) Comments on the PRA:

NAAA

1. **NAAA Conclusion:**
   NAAA is concerned that the Tier 1 level is being used in the AgDRIFT drift models for the risk assessments of Paraquat. The assumptions made in the Tier 1 model do not accurately reflect how modern agricultural aircraft are setup to apply pesticides.

   EPA Response: This response is limited to the ecological risk assessment and does not cover comments on the human health risk assessment.

   AgDRIFT™ is the currently approved model for evaluating potential spray drift from a pesticide application. The Agency appreciates the additional information on application practices (both ground and aerial) and continues to work with industry to update and improve modeling methods to better reflect these practices. Modeling in the paraquat exposure assessment is based on label instructions and in the absence of specific application requirements, default assumptions are used. Additionally, the risk assessment provided outputs for risks associated with ground and aerial applications, which will allow risk managers to understand the range of risks associated with different application methods.

With respect to NAAA's recommendation to alter the existing temperature inversion language on pesticide labels, EPA believes that the terms "at or near the ground-level" do not provide adequate clarification, given the difficulty of defining the altitude where inversion conditions may not impact drift. Thus, the Agency is not specifying "at or near the ground-level." However, NAAA is correct that the intention of the language is to prohibit pesticide application during temperature inversions that occur where the applicator is present.

Washington State Department of Agriculture (WSDA) Comments on the PRA:

WSDA Comments 1-5 in the comment submission referred to the Draft Human Health Risk Assessment and are not addressed here.

Specific comments on the document *"Paraquat: Preliminary Ecological Risk Assessment for Registration Review"*:

WSDA Comment 6, page 70—in Table 10-2. Default Tier 1 Adult, Acute Contact Risk for Honey Bees Foraging on Paraquat-Treated Plants, under the Bee Attractiveness column, the statement contains an extra word. The word "has" should be removed. Y (pollen & nectar) Attractive in all cases, except for alfalfa pollen which ~~has~~ is opportunistically attractive.

EPA Response: The Agency acknowledges the extra word (typo). As suggested, the cell under Bee Attractiveness should read: "Y (pollen & nectar) Attractive in all cases, except for alfalfa pollen which is opportunistically attractive".

WSDA Comment 7, Page 106 and 107—in Appendix A. ROCKs table, Table B1. Chemical Names and Structures of Paraquat and its Transformation Products, there are highlighted question marks (?) in blue. What is the significance of the blue highlighting?

EPA Response: The question marks appear next to very old studies (MRID numbers that begin with "00") that could not be located in the Agency's information storage systems. The intent was to indicate that the document could not be located, and the information (the percent of applied radioactivity and the day of the study that it was measured) could not be reconstructed from data summaries found in other documents. The Agency acknowledges there should have been a footnote to this table indicating as much.

WSDA Comment 8, pages 132, 134, 135, and 136—seven instances of the word "addendium" in the table titled Tier II Vegetative Vigor 850.4150. Should the word used be "addendum" instead?

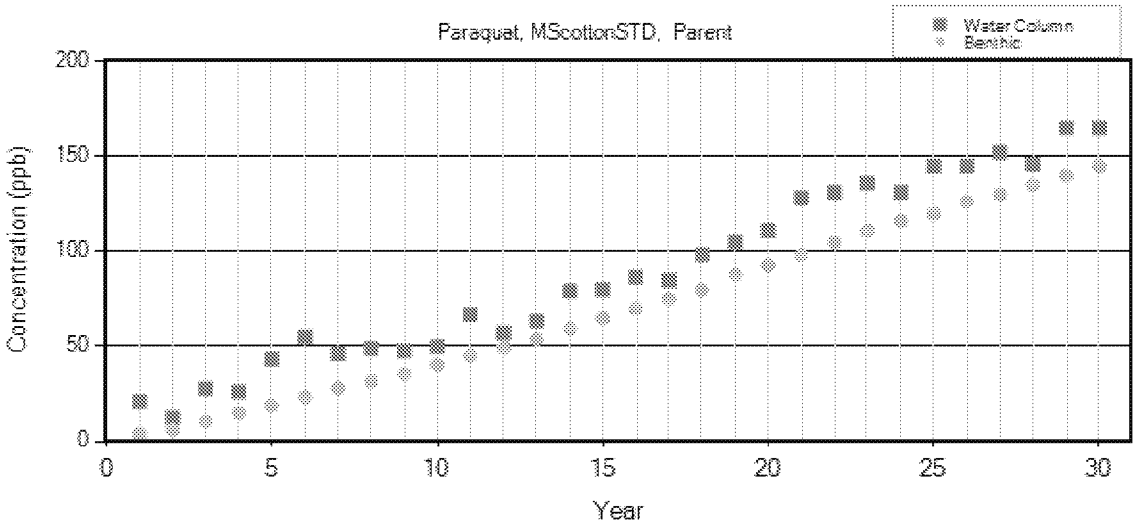
EPA Response: The Agency acknowledges that in **Table B-3** "addendum" is misspelled multiple times.

WSDA Comment 9, page 142— Table is incomplete. This page contains an empty box with the words:

The image part with relationship ID r1d49 was not found in the file.

The preceding page indicates it is supposed to be information relating to Figure 1. Yearly Peak Concentrations

EPA Response: Some of the images in this document did not translate properly during a file conversion in the publication process. The Agency apologizes for the confusion. **Appendix C. Example Aquatic Modeling Output** – the image identified as "**Figure 1. Yearly Peak Concentrations**" should be as follows:



WSDA Comment 10, page 143-- Table is incomplete. Appendix D. Example Output for Terrestrial Modeling contains an empty box with the words:

The image part with relationship ID rld50 was not found in the file.

The table indicates that it is supposed to contain Seeding Rate (lbs/acre)

TREX MODEL INPUTS	
These values will be used in the calculation of exposure estimates for foliar, granular, li applications of pesticides.	
Chemical Identity and Application Information	
Chemical Name:	Paraquat
Seed Treatment? (Check if yes)	The image
Use:	Clover
Product name and form:	Paraquat Cation
% A.I. (leading zero must be entered for formulations <1% a.i.):	100.00%

EPA Response: Some of the images in this document did not translate properly during a file conversion in the publication process. The Agency apologizes for the confusion. Because some of the TREX output images had parts that did not convey properly, each of the questions is addressed in the following responses. The above lost image was a box that is used when seed treatments are assessed. The pull-down menu that goes with it is copied below, but was not used here. The spreadsheet containing the program also shows options that are referenced here. It is available for download at: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#terrestrial

Seed Treatment? (Check if yes) ☐
Use:
Product name and form:
% A.I. (leading zero must be ...tered for formulations <1% a.i.):
Application Rate (lb ai/acre)
Half-life (days):

corn, all or unspecified
corn, field
corn, pop
corn, sweet
cotton, all or unspecified
cotton, pima
rice
soybean

WSDA Comment 11, page 144— Table is incomplete. This page contains Endpoints tables for Avian and Mammalian studies, the table contains 5 "blank" boxes containing the words:

The image part with relationship ID rld51 was not found in the file.
The image part with relationship ID rld52 was not found in the file.
The image part with relationship ID r1d53 was not found in the file.
The image part with relationship ID r1d54 was not found in the file.
The image part with relationship ID r1d55 was not found in the file.

It appears these boxes should contain test species.

Endpoint	Toxicity value	Indicate test species below		weig ht (g)	Nam e	Toxicity Value Reference (MRID)
LD50 (mg/kg-bw)	26.50	The image part with relationship ID rld51 was		14.30	Zebr a Finch	49349901
LC50 (mg/kg-diet)	698.00	The image part with relationship ID rld52 was		43.00	Japa nese Quail	00022923 (got wt. from CRLF TREX sheet)
NOAEL (mg/kg-bw)		The image part with relationship ID rld53 was				
NOAEC (mg/kg-diet)	29.40	The image part with relationship ID rld54 was				110455
Enter the Mineau et al. Scaling Factor		1.15				
Mammalian						
		Acute Study	Chronic Study			
Size (g) of mammal used in toxicity study Default rat body weight is 350 grams		350	350			
Endpoint	Toxicity value		Reference (MRID)			
LD50 (mg/kg-bw)	93.00		43685001			
LC50 (mg/kg-diet)						
Reported Chronic Endpoint	7.50	The image part with relationship ID	126783 NOTE: No LOAEC			

EPA Response: This table should appear as:

Avian						
Endpoint	Toxicity value	Indicate test species below		Optional Test Organism Body weight (g)	Optional Test Species Name	Toxicity Value Reference (MRID)
LD50 (mg/kg-bw)	26.50	Other		14.30	Zebra Finch	49349901
LC50 (mg/kg-diet)	698.00	Other		43.00	Japanese Quail	00022923 (got wt. from CRLF TREX sheet)
NOAEL (mg/kg-bw)		Mallard duck				
NOAEC (mg/kg-diet)	29.40	Mallard duck				110455
Enter the Mineau et al. Scaling Factor		1.15				
Mammalian						
		Acute Study	Chronic Study			
Size (g) of mammal used in toxicity study Default rat body weight is 350 grams		350	350			
Endpoint	Toxicity value		Reference (MRID)			
LD50 (mg/kg-bw)	93.00		43685001			
LC50 (mg/kg-diet)						
Reported Chronic Endpoint	7.50	mg/kg-bw	126783 NOTE: No LOAEC			
Is dietary concentration (mg/kg-diet) reported from the available chronic mammal study? (yes or no)	yes					
Enter dietary concentration (mg/kg-diet)	108.00					

WSDA Comment 12, page 146—Table is incomplete. Table X. Upper Bound Kenaga, Acute Mammalian Dietary Based Risk Quotients. Table contains 5 instances of missing/uncalculated RQ values as denoted by "#DIV/0!."

Table X. Upper Bound Kenaga, Acute Mammalian Dietary Based Risk Quotients										
	EECs and RQs									
	Short Grass		Tall Grass		Broadleaf Plants		Fruits/Pods/Seeds		Arthropods	
LC50 (ppm)	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ	EEC	RQ
0	396.54	#DIV/0!	181.75	#DIV/0!	223.05	#DIV/0!	24.78	#DIV/0!	155.31	#DIV/0!
Size class not used for dietary risk quotients										

EPA Response: The notation #DIV/0!" is how the program responds when it is asked to divide by zero and this is because there was no available mammalian acute dietary endpoint for risk calculations. In this case, it means – Information Not Available.

WSDA Comment 13, page 148, Table titled Avian. Table is incomplete. Table contains 4 "blank" boxes containing the words:

The image part with relationship ID r1d56 was not found in the file.
The image part with relationship ID r1d57 was not found in the file.
The image part with relationship ID r1d58 was not found in the file.
The image part with relationship ID r1d59 was not found in the file.

It appears the boxes are supposed to contain the test species.

Avian			
Endpoint	Toxicity value	Indicate test species below	
LD50 (mg/kg-bw)	26.50	The image part with relationship ID rld56 was	
LC50 (mg/kg-diet)	698.00	The image part with relationship ID rld57 was	
NOAEL (mg/kg-bw)		The image part with relationship ID rld58 was	
LOAEC (mg/kg-diet)	101.00	The image part with relationship ID rld59 was	

EPA Response: This table should appear as:

Avian			
Endpoint	Toxicity value	Indicate test species below	
LD50 (mg/kg-bw)	26.50	Other	
LC50 (mg/kg-diet)	698.00	Other	
NOAEL (mg/kg-bw)		Mallard duck	
LOAEC (mg/kg-diet)	101.00	Mallard duck	

WSDA Comment 14, page 150—Table is incomplete. Table titled TREX Runs Using the Additional Line-of-Evidence for Mammals — PreNatal Growth Endpoint contains 2 "blank" boxes containing the words:
The image part with relationship ID rld60 was not found in the file.
The image part with relationship ID rld61 was not found in the file.

It is unclear what the boxes are intended to contain.

Mammalian			
		Acute Study	
Size (g) of mammal used in toxicity study Default rat body weight is 350 grams		350	
Endpoint	Toxicity value		R
LD50 (mg/kg-bw)	93.00		
LC50 (mg/kg-diet)			
Reported Chronic Endpoint	1.00	The image part with relationship ID rld61 was	

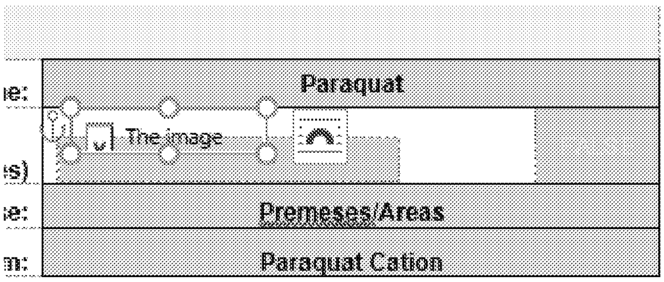
EPA Response: This table should have shown a pull-down menu with the option mg/kg-bw selected, as shown below:

Mammalian			
		Acute Study	Chronic Study
Size (g) of mammal used in toxicity study Default rat body weight is 350 grams		350	350
Endpoint	Toxicity value		Reference (MRID)
LD50 (mg/kg-bw)	93.00		43685001
LC50 (mg/kg-diet)			
Reported Chronic Endpoint	1.00	mg/kg-bw	113714

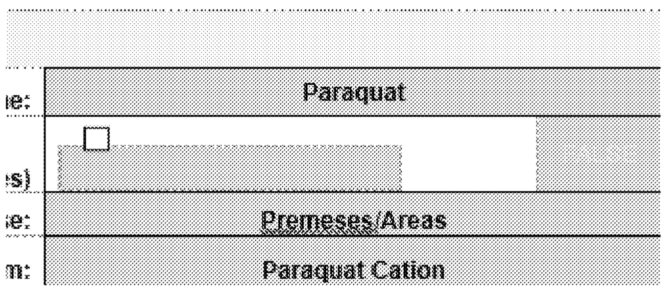
WSDA Comment 15, page 152—Table is incomplete. Table titled Chemical Identity and Application Information contains a "blank" box containing the words:

The image part with relationship ID r1d62 was not found in the file.

It is unclear what the box is intended to contain.



EPA Response: The missing image should have been a box to check if doing seed treatment analysis, shown below:



WSDA Comment 16, page 155—Table is incomplete. Table titled Chemical Identity and Application Information contains a "blank" box containing the words:

The image part with relationship ID r1d63 was not found in the file.

It is unclear what the box is intended to contain.

WSDA Comment 17, page 157—Table is incomplete. Table titled Chemical Identity and Application Information contains a "blank" box containing the words:

The image part with relationship ID r1d64 was not found in the file.

It is unclear what the box is intended to contain.

WSDA Comment 18, page 159—Table is incomplete. Table titled Chemical Identity and Application Information contains a "blank" box containing the words:

The image part with relationship ID r1d65 was not found in the file.

It is unclear what the box is intended to contain.

EPA Response to WSDA Comments 16, 17, and 18: Same as above, see response to Comment 15. The missing image should have been a box to check if doing seed treatment analysis, not re-copied here.

WSDA Comment 19, page 161—top of page indicates that *"Input and output guidance is in popups indicated by red arrows,"* but red arrows are not present on screen.

EPA Response: This statement was in the spreadsheet with the purpose of giving direction to the user; however, the appendix contains a copied image and the popups did not convey. An example is shown here for one of the input values and is seen by hovering over the red arrow:

Table 2. Input parameters used to derive EECs.

Input Parameter	Symbol	Value	Units
Application Rate	A	1.5	
Incorporation	I	1	
Runoff Fraction	R	0.05	none
Drift Fraction	D	0.05	none

The maximum single application rate according to the label.

A copy of the model/spreadsheet is available for download at: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment#terrestrial

WSDA Comment 20, page 162—Table is incomplete. Table 4. Daily consumption of food, pesticide dose and resulting dietary RQs for all bees. Table contains instance of missing/uncalculated Acute RQ values as denoted by "#DIV/0!."

EPA Response: The Excel notation #DIV/0!" means that the calculation was not made - Information Not Available. For bees, only acute adult data were available for this assessment, and the data needs for a more complete pollinator assessment were listed in **Section 1.5** and other places.

WSDA Comment 21, page 162—Table is incomplete. Table 5. Results (highest RQs). Table contains 3 instances of missing/uncalculated values as denoted by "#DIV/0!."

EPA Response: Same as above. See response to Comment 20. The notation #DIV/0!" means that the calculation was not made - Information Not Available.

WSDA Comment 22, page 162—three random instances of "µg ailmg" appear on the page. Is there a missing table?

EPA Response: These are relics of the spreadsheet's unused options.

WSDA Comment 23, page 163—Table is incomplete. Table 4. Daily consumption of food, pesticide dose and resulting dietary RQs for all bees (header found on pervious page) contains 9 instances of missing/uncalculated values as denoted by "#DIV/0!."

EPA Response: As in response to Comments 12 and 21, the complete dataset was not available in this run. The notation #DIV/0!" means that the calculation was not made - Information Not Available.

WSDA Comment 24, page 164—Tables/information are incomplete. Tables titled AgDrift Output:, Aerial Applications:, Fine Droplets: Information contains 4 "blank" boxes containing the words:

The image part with relationship ID r1d66 was not found in the file.
The image part with relationship ID r1d67 was not found in the file.
The image part with relationship ID r1d68 was not found in the file.
The image part with relationship ID r1d69 was not found in the file.

It is unclear what the boxes are intended to contain.

EPA Response: Some of the images in this document did not translate properly during a file conversion in the publication process. The Agency apologizes for the confusion. The AgDrift output for pollinators was revised to correct an endpoint and is copied above in response to Syngenta Comment #7.

WSDA Comment 25, page 165, 166 & 167—table/information is incomplete. Table titled Appendix E. Incident Report Outputs, Aggregate Incident Reports--PC Codes 061601 (Paraquat Dichloride) and 061603 (Paraquat): contain a blank box on each of these pages containing the words:

The image part with relationship ID rld70 was not found in the file.
The image part with relationship ID rld71 was not found in the file.
The image part with relationship ID r1d72 was not found in the file.

It is unclear what the boxes are intended to contain.

EPA Response: The images are copied below (on the next three pages):

Aggregate Incident Report for EFED

Paraquat dichloride

PC Code: 061601

Date Range	*Package*	*Page*	*Product*	*Sum*	*W-B*	*P-B*	*ONT*
10/1/1995 - 10/31/1995	002905	60	ORTHO PARAQUAT CONCENTRATE 3	9	0	9	0
11/1/1995 - 11/30/1995	002944	25	ORTHO PARAQUAT CONCENTRATE 3	4	0	4	0
8/1/1996 - 8/31/1996	004197	57	ORTHO PARAQUAT CONCENTRATE 3	1	0	1	0
5/1/1997 - 5/31/1997	005463	75	ORTHO PARAQUAT CONCENTRATE 3	2	0	2	0
4/1/1998 - 6/30/1998	007666	4	GRAMOXONE EXTRA	8	0	8	0
7/1/1998 - 9/30/1998	008036	9	GRAMOXONE EXTRA	5	0	5	0
10/1/1998 - 12/31/1998	008409	8	GRAMOXONE EXTRA	2	0	2	0
1/1/1999 - 3/31/1999	008691	7	GRAMOXONE EXTRA	3	0	3	0
4/1/1999 - 6/30/1999	009143	17	GRAMOXONE EXTRA HERBICIDE	15	1	14	0
7/1/1999 - 9/30/1999	009604	12	GRAMOXONE EXTRA HERBICIDE	5	0	5	0
10/1/1999 - 12/31/1999	009851	9	STARFIRE	1	0	0	1
1/1/2000 - 3/31/2000	010217	30	GRAMOXONE EXTRA	1	0	0	1
4/1/2000 - 6/30/2000	010623	4	GRAMOXONE EXTRA	16	0	15	1
7/1/2000 - 9/30/2000	010907	10	GRAMOXONE EXTRA	1	0	1	0
10/1/2000 - 12/31/2000	011191	4	STARFIRE	1	0	1	0
4/1/2001 - 6/30/2001	011976	5	GRAMOXONE	2	1	1	0
11/1/2001 - 10/31/2002	013554	59	GRAMOXONE EXTRA	1	0	1	0
11/1/2001 - 10/31/2002	013554	59	GRAMOXONE MAX	1	0	1	0

Data in this report are derived from the Aggregate Summary Module of OPP's Incident Database, maintained by the Information Services Branch of the Information Technology and Resource Management Division.

Date Range	Package	Page	Product	Sum	W-B	P-B	ONT
1/1/2002 - 3/31/2002	012923	3	GRAMOXONE EXTRA	1	1	0	0
7/1/2002 - 9/30/2002	013556	3	GRAMOXONE MAX	1	0	1	0
4/1/2004 - 6/30/2004	015395	3	GRAMOXONE MAX	1	0	1	0
7/1/2004 - 9/30/2004	015707	3	GRAMOXONE MAX	1	1	0	0
4/1/2007 - 6/30/2007	018826	4	PARAQUAT DICHLORIDE	1	0	1	0
4/1/2008 - 6/30/2008	019981	8	GRAMOXONE (NON-SPECIFIC)	1	0	1	0
7/1/2008 - 9/30/2008	020310	1	FIRESTORM	1	0	1	0

Data in this report are derived from the Aggregate Summary Module of OPP's Incident Database, maintained by the Information Services Branch of the Information Technology and Resource Management Division.

Aggregate Incident Report for EFED

Paraquat

PC Code: 061603

Date Range	*Package*	*Page*	*Product*	*Sum*	*W-B*	*P-B*	*ONT*
4/1/2004 - 6/30/2004	015395	3	GRAMOXONE	1	0	0	1

Data in this report are derived from the Aggregate Summary Module of OPP's Incident Database, maintained by the Information Services Branch of the Information Technology and Resource Management Division.

Thursday, June 14, 2018 *Page 1 of 1*

Appendix A: Revisions to the PRA.

Revisions (in red text) on p. 6 of the assessment:

Table 1-1. Summary of Risk Quotients for Taxonomic Groups from Current Uses of Paraquat.

Taxa	Exposure Duration	Risk Quotient (RQ) Range[1]	RQ Exceeding the LOC for Non-listed Species	Additional Information/ Lines of Evidence
Terrestrial invertebrates	Acute Adult	0.01-1.6	Yes	Oral exposure risks exceeding the LOC for all uses and for the lowest single application rate for two honey bee castes. Contact exposure risks not exceeding the LOC for any uses. Multiple uses have the potential to attract pollinators, but application timing, as well as distances of 4-23 feet, coarse droplet size specifications can remove the presumption of risk to adult bees from acute contact exposure from spray drift. One hive damage incident was of 'possible' causality but of 'undetermined' legality, suggesting potential for harm to pollinators but link to registered use not clearly substantiated. More information is needed to fully assess risks to bees.
	Chronic Adult	No data	No data	
	Acute Larval	No data	No data	
	Chronic Larval	No data	No data	

Revisions (in red text) on p. 23 of the assessment:

Table 6-2. Terrestrial Toxicity Endpoints Selected for Risk Estimation for Paraquat

Study Type	**Test Substance (% a.i.)**	**Test Species**	**Toxicity Value**	**MRID or ECOTOX No./ Classification**	**Comments**
Terrestrial Invertebrates					
Acute Contact (adult)	TEP: EC Formulation with 25.2% cation	Honey bee *Apis mellifera* L.	LD_{50} = 72 µg cation/bee	43942603 Acceptable	Practically Nontoxic.
Acute Oral (adult)	TEP: EC Formulation with 25.2% cation	Honey bee *A. mellifera* L.	LD_{50} = 31 µg cation/bee	43942603 Acceptable	Practically Nontoxic.

Revisions (in red text) on p. 61 of the assessment:

Table 9-4. Chronic RQs for Mammals from Labeled Uses of Paraquat (T-REX v. 1.5.2, Upper Bound Kenaga)

Food Type	RQs Based on Multi-Gen. Rat Study				Additional Line-of-Evidence Exposure:Effect Ratios (RQ Estimates) Based on Pre-Natal Data NOAEL = 1 mg cation/kg-bw[1]		
	Chronic Dose-Based RQ NOAEL = 7.5 mg cation/kg-bw[1]			Chronic Dietary RQ NOAEC = 150 mg cation/kg-diet[1]			
	Small (15 g)	Medium (35 g)	Large (1000 g)		Small (15 g)	Medium (35 g)	Large (1000 g)
Alfalfa and Clover (1.5 lb cation/acre, 3x, 120-day interval)[2]							
Herbivores/Insectivores							
Short grass	**22.9**	**19.6**	**10.5**	2.64	**172**	**147**	**78.8**
Tall grass	**10.5**	**8.98**	**4.81**	1.21	**78.8**	**67.4**	**36.1**
Broadleaf plants	**12.9**	**11.0**	**5.91**	1.49	**96.8**	**82.7**	**44.3**
Fruits/pods/seeds	**1.43**	**1.22**	0.66	0.17	**10.8**	**9.18**	**4.92**
Arthropods	**8.98**	**7.67**	**4.11**	1.04	**67.4**	**57.6**	**30.9**
Granivores							
Seeds	0.32	0.27	0.15	0.17	**2.39**	**2.04**	**1.09**
Premises/Areas (1.01 lb cation/A, 10x, 7-day interval)							
Herbivores/Insectivores							
Short grass	**81.2**	**69.4**	**37.2**	9.36	**609**	**520**	**279**
Tall grass	**37.2**	**31.8**	**17.1**	4.29	**279**	**239**	**128**
Broadleaf plants	**45.7**	**39.0**	**20.9**	5.27	**343**	**293**	**157**
Fruits/pods/seeds	**5.08**	**4.34**	**2.32**	0.59	**38.1**	**32.5**	**17.4**
Arthropods	**31.8**	**27.2**	**14.6**	3.67	**239**	**204**	**109**
Granivores							
Seeds	**1.13**	0.96	0.52	0.59	**8.46**	**7.23**	**3.87**
Multiple Ag and Non-Ag Uses (1.01 lb cation/A, 5x, 7-day interval)							
Herbivores/Insectivores							
Short grass	**54.2**	**46.3**	**24.8**	6.24	**406**	**347**	**186**
Tall grass	**24.8**	**21.2**	**11.4**	2.86	**186**	**159**	**85.2**
Broadleaf plants	**30.5**	**26.0**	**14.0**	3.51	**228**	**195**	**105**
Fruits/pods/seeds	**3.38**	**2.89**	**1.55**	0.39	**25.4**	**21.7**	**11.6**
Arthropods	**21.2**	**18.1**	**9.71**	2.44	**159**	**136**	**72.8**
Granivores							
Seeds	0.75	0.64	0.34	0.39	**5.64**	**4.82**	**2.58**
Single App. (1.01 lb cation/A)							
Herbivores/Insectivores							
Short grass	**14.0**	**12.0**	**6.42**	1.62	**105**	**89.8**	**48.2**
Tall grass	**6.43**	**5.49**	**2.94**	0.74	**48.2**	**41.2**	**22.1**
Broadleaf plants	**7.89**	**6.74**	**3.61**	0.91	**59.2**	**50.5**	**27.1**
Fruits/pods/seeds	0.88	0.75	0.40	0.10	**6.57**	**5.61**	**3.01**
Arthropods	**5.49**	**4.69**	**2.51**	0.63	**41.2**	**35.2**	**18.9**
Granivores							
Seeds	0.19	0.17	0.09	0.10	**1.46**	**1.25**	0.67
Single App. Lower Rate (0.50 lb cation/A)							

Herbivores/Insectivores							
Short grass	**6.94**	**5.93**	**3.18**	0.80	**18.4**	**15.8**	**8.44**
Tall grass	**3.18**	**2.72**	**1.46**	0.37	**7.81**	**6.67**	**3.58**
Broadleaf plants	**3.90**	**3.33**	**1.79**	0.45	**9.76**	**8.34**	**4.47**
Fruits/pods/seeds	0.43	0.37	0.20	0.05	**1.52**	**1.30**	0.70
Arthropods	**2.72**	**2.32**	**1.24**	0.31	**14.1**	**12.0**	**6.46**
Granivores							
Seeds	0.10	0.08	0.04	0.05	0.34	0.29	0.15

Bolded values exceed the chronic risk LOC of 1.0. The endpoints listed in the table are the endpoint used to calculate the RQ.
[1]The toxicity endpoint used in RQ calculations, Rat LD_{50} (MRID 43685001), had no measurable effects in reproductive or offspring body weight at the highest treatment level of 7.5 mg cation/kg-bw (108 mg cation/kg-diet). Due to the non-definitive LOAEC.and additional line-of-evidence was added by estimating risk using a growth endpoint from a prenatal developmental study.
[2]Alfalfa has a 1.5 lb a.e./A max with 1 app. per crop cycle, and specifies 3 apps per year, but also has a 2 lb a.e./A annual max, so although this screening for alfalfa and clover is represented here using 3 apps, the ann. amount is over-estimated for alfalfa. The clover use does not currently specify the ann. no. of apps or the ann. max. amount.

Revisions (in red text) on p. 69 of the assessment:

Table 10-2. Default Tier 1 Adult, Acute Contact Risk for Honey Bees Foraging on Paraquat-Treated Plants

Use Pattern	Bee Attractiveness	Max. Single Application Rate	Dose (µg cation/bee per 1 lb cation/A)[1]	Paraquat Contact Dose (µg cation/bee)	Acute RQ[2]
Alfalfa and Clover	Y (pollen & nectar) Attractive in all cases, except for alfalfa pollen which has is opportunistically attractive	1.5 lb cation/A	4.1 (165 mg cation/kg)	72	0.06

No values are bolded; **Bolded** RQ value exceeds (or potentially exceeds) the acute risk LOC of 0.4. No exceedances.
[1] Source: USEPA 2014. Guidance for Assessing Pesticide Risks to Bees
[2] Based on a 48-h acute contact LD_{50} of 72 µg cation/bee for paraquat (MRID 43942603).

Revisions (in red text) on p. 70-71 of the assessment:

On-Field Risk

For oral exposure, the Tier 1 assessment considers just the caste of bees with the greatest oral exposure (foraging adults). If risks are identified, then other factors are considered for refining the Tier 1 risk estimates. These factors include other castes of bees and available information on residues in pollen and nectar which is deemed applicable to the crops of interest.

Based on acute oral toxicity, four out of seven castes of adult bees had LOC exceedances at the highest single application rate (1.5 lb cation/A) for alfalfa and clover (**Table 10-3**, also see **Appendix D**). For the highest and lowest single application rates (1.01 and 0.5 lb cation/A, respectively) for all other uses (a few had rates between these highest and lowest rates), two castes had LOC exceedances, workers foraging for nectar and drones. Worker nurse bees tending brood and queen also had LOC exceedance with the higher rate (1.01 lb cation/A).

Table 10-3. Tier 1 (Default) Oral Risk Quotients for Adult Nectar Forager and Worker Honey Bees

Use Pattern	Max. Single Appl. Rate	Bee Caste/Task	Unit Dose (μg a.i./bee per 1 lb a.i./A)[1]	Oral Dose (μg a.i./bee)	Acute Oral RQ[2,3,4]
Alfalfa and Clover	1.5 lb cation/A	Worker (cell cleaning and capping)	4.1	11.0	0.35
		Worker (brood and queen tending, nurse bees)		25	**0.79**
		Worker (comb building, cleaning and food handling)		10	0.33
		Worker (foraging for pollen)		7.2	0.23
		Worker (foraging for nectar)		48	**1.6**
		Worker (maintenance of hive in winter)		5.1	0.17
		Drone		39	**1.3**
		Queen (laying 1500 eggs/day)		0.87	0.03
Multiple Uses – Highest Single Application Rate	1.01 lb cation/A	Worker (cell cleaning and capping)	2.7	7.4	0.24
		Worker (brood and queen tending, nurse bees)		17	**0.54**
		Worker (comb building, cleaning and food handling)		6.9	0.22
		Worker (foraging for pollen)		4.8	0.16
		Worker (foraging for nectar)		32	**1.0**
		Worker (maintenance of hive in winter)		3.4	0.11
		Drone		26	**0.84**
		Queen (laying 1500 eggs/day)		0.58	0.019
Multiple Uses – Lower Rate	0.5 lb cation/A	Worker (cell cleaning and capping)	1.4	3.7	0.12
		Worker (brood and queen tending, nurse bees)		8.2	0.27
		Worker (comb building, cleaning and food handling)		3.4	0.11
		Worker (foraging for pollen)		2.4	0.08
		Worker (foraging for nectar)		16	**0.51**

Use Pattern	Max. Single Appl. Rate	Bee Caste/Task	Unit Dose (µg a.i./bee per 1 lb a.i./A)[1]	Oral Dose (µg a.i./bee)	Acute Oral RQ[2,3,4]
		Worker (maintenance of hive in winter)		1.7	0.055
		Drone		13	**0.42**
		Queen (laying 1500 eggs/day)		0.29	0.009

[1] Source: USEPA 2014. Guidance for Assessing Pesticide Risks to Bees.
[2] Based on a 48-h acute oral LD_{50} of 31 µg cation/bee for adults (MRID 43942603).
[3] **Bolded** RQ value exceeds (or potentially exceeds) the acute risk LOC of 0.4 or chronic LOC of 1.0
[4] Information on chronic effects not available.

Revisions (in red text) on p. 72-73 of the assessment:

Off-Field Risk

In addition to bees foraging on the treated field, bees may also be foraging in fields adjacent to the treated fields. AgDrift analysis showed that distances needed to remove the presumption of risk for the bee caste at highest risk (workers foraging for nectar) were:

- 4 to 23 feet for the highest application rate (1.5 lb cation/A) for alfalfa and clover;
- 4 to 7 feet at the highest application rate for most uses (1.01 lb cation/A); and
- <1 to 4 feet at the lowest application rate for most uses (0.5 lb cation/A).

Coarse droplet size (and low boom for ground applications) roughly halved the distance applying to fine droplets (and high boom) and similarly, aerial applications required approximately twice the distance for the highest application rate. As a clarification, even though BeeRex calculated LOC exceedance at the lower rate (0.5 lb cation/A), the aerial calculations from the AgDrift model were slightly different and were already below the fraction to remove the presumption of risk at the edge of the field (**Table 10-4**, also see **Appendix D**).

Table 10-4. AgDrift Tier 1 Distances to Remove the Presumption of Oral Risk to Adult Nectar Forager and Worker Honey Bees

Use, Single Application Rate	Fraction of Application Rate That Would Remove the Presumption of Risk[1]	For Aerial Application: Estimated Distance from Edge of Field to Approximate Fraction, feet		For Ground Application: Estimated Distance from Edge of Field, feet	
		Fine Droplet Size[2]	Coarse Droplet Size[3]	Fine Droplet Size[2] / High Boom	Coarse Droplet Size[3] / Low Boom
Based on Worker Foraging for Nectar					
Alfalfa and Clover, 1.5 lb cation/A	0.25	23	14	14	4
Multiple Uses, 1.01 lb cation/A	0.40	7	7	7	4
Multiple Uses, 0.5 lb cation/A	0.78	<1	<1	4	4

[1]This is the fraction of the highest calculated caste RQ from BeeRex (**Table 10-3**) that would equal the LOC of 0.4 for pollinators.

[2]Based on a tier 1 aerial-spray and ground-spray scenarios with high boom application (for ground), ASAE very fine to fine drop spectrum (fine to medium for aerial/fine to very fine for ground) and 90th percentile exposure.
[3] Based on a tier 1 aerial-spray and ground-spray scenarios with low boom application (for ground), ASAE medium/coarse drop spectrum (course to very coarse for aerial/fine to medium/coarse for ground) and 90th percentile exposure.

Revisions (in red text) on p. 124 of the assessment:

Table B-2. Summary of Terrestrial Toxicity Data for Paraquat Expressed as Paraquat Cation.

Species Tested	Guideline Note (if Applicable) Test Substance: % a.i.	Toxicity Value (95% C.I. or standard deviation if noted) Slope (if applicable)	MRID (or other Citation) Classification NEW Studies Noted	Notes
Toxicity to Honey Bees 850.3020 (or equivalent §141-1); the oral test is currently non-guideline:				
Honey Bee *Apis mellifera L.*	Acute Contact TEP: EC Formulation containing 1.67 lb/gal paraquat dichloride (estimated to be 25.2% - see Notes)	48-hr LD_{50} = 72 µg cation/bee	43942603 Acceptable	**Most sensitive/defensible honey bee acute contact endpoint:** LD_{50} = 72 µg cation/bee. Available data suggest that formulated paraquat is more toxic than the TGAI. The DER did not provide the % purity except as lb paraquat dichloride/gal. Used a label for Gramoxone SL to calculate the purity. The label was for a 2.0 lb paraquat cation/gal formulation and specified 30.1% cation. Used the following ratio calculation to estimate the percent: 2.0 / 0.301 = 6.74 (cation/gal if 100%); 1.67 / 6.74 = 0.252; so 25.2%.
Honey Bee *A. mellifera*	Acute Contact TGAI: at least 95%	48-hr LD_{50} >35 µg cation/bee	05001991 Acceptable	This is an open lit submission (Stevensen, 1978).
Honey Bee *A. mellifera*	Acute Contact TGAI: 99%	48-hr LD_{50} >144 µg cation/bee	43942603 Acceptable	
Honey Bee *A. mellifera*	Acute Oral TEP: EC Formulation containing 1.67 lb/gal paraquat dichloride (25.2% cation)	48-hr LD_{50} = 31 µg cation/bee	43942603 Acceptable	**Most sensitive/defensible honey bee acute oral endpoint:** LD_{50} = 31 µg cation/bee. Available data suggest that formulated paraquat is more toxic than the TGAI and that paraquat is more toxic as an oral dose than a contact dose.

Species Tested	Guideline Note (if Applicable) Test Substance: % a.i.	Toxicity Value (95% C.I. or standard deviation if noted) Slope (if applicable)	MRID (or other Citation) Classification NEW Studies Noted	Notes
				For purity estimate, see Notes for the contact study.
Honey Bee *A. mellifera*	Acute Oral TGAI: 99%	48-hr LD_{50} = 51 µg cation/bee	43942603 Acceptable	

Revisions (in red text) on p. 162-164 of the assessment:

BeeRex Output:

Table 1. User inputs (related to exposure)

Description	Value
Application rate	1.5
Units of app rate	lb a.i./A
Application method	foliar spray
Are empirical residue data available?	no

Table 5. Results (highest RQs)

Exposure	Adults	Larvae
Acute contact	0.05625	NA
Acute dietary	1.55	#DIV/0!
Chronic dietary	#DIV/0!	#DIV/0!

µg a.i./mg

µg a.i./mg

µg a.i./mg

Table 2. Toxicity data

Description	Value (µg a.i./bee)
Adult contact LD50	72
Adult oral LD50	31
Adult oral NOAEL	
Larval LD50	
Larval NOAEL	

Table 3. Estimated concentrations in pollen and nectar

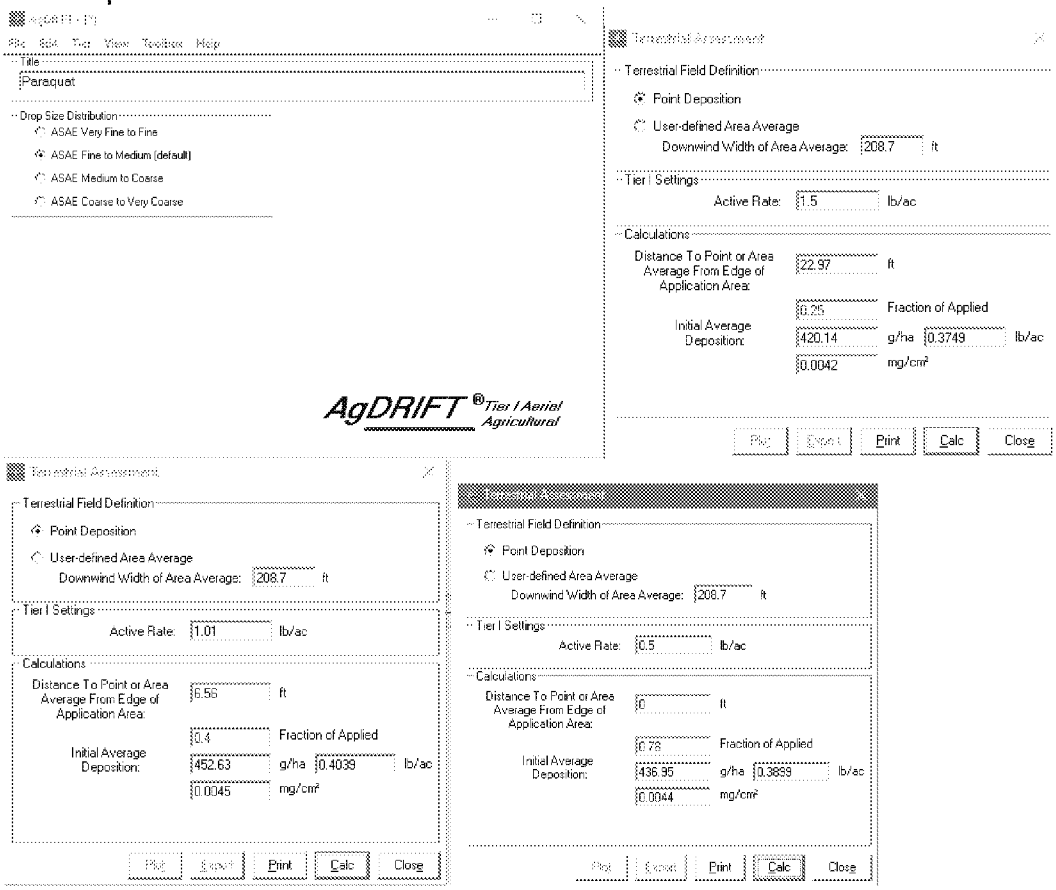
Application method	EECs (mg a.i./kg)	EECs (µg a.i./mg)
foliar spray	165	0.165
soil application	NA	NA
seed treatment	NA	NA
tree trunk	NA	NA

Table 4. Daily consumption of food, pesticide dose and resulting dietary RQs for all bees

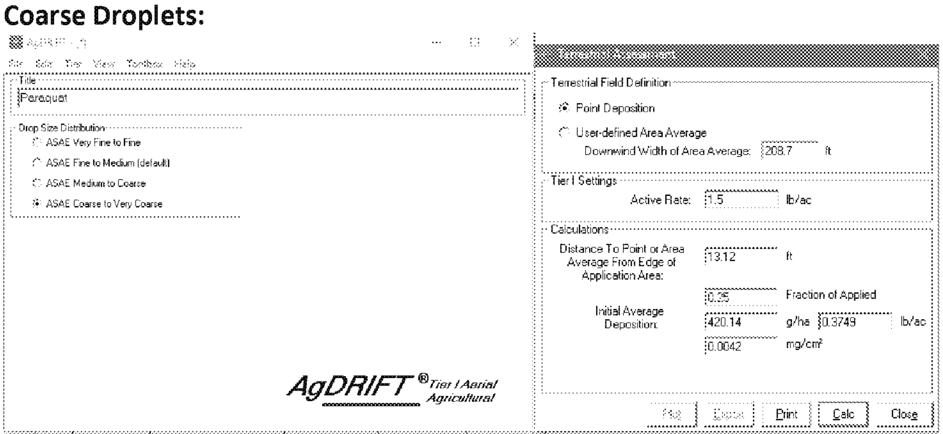
Life stage	Caste or task in hive	Average age (in days)	Jelly (mg/day)	Nectar (mg/day)	Pollen (mg/day)	Total dose (µg a.i./bee)	Acute RQ
Larval	Worker	1	1.9	0	0	0.003135	#DIV/0!
		2	9.4	0	0	0.01551	#DIV/0!
		3	19	0	0	0.03135	#DIV/0!
		4	0	60	1.8	10.197	#DIV/0!
		5	0	120	3.6	20.394	#DIV/0!
	Drone	6+	0	130	3.6	22.044	#DIV/0!
	Queen	1	1.9	0	0	0.003135	#DIV/0!
		2	9.4	0	0	0.01551	#DIV/0!
		3	23	0	0	0.03795	#DIV/0!
		4+	141	0	0	0.23265	#DIV/0!
Adult	Worker (cell cleaning and capping)	0-10	0	60	6.65	10.99725	0.35475
	Worker (brood and queen tending, nurse bees)	6 to 17	0	140	9.6	24.684	0.79625806
	Worker (comb building, cleaning and food handling)	11 to 18	0	60	1.7	10.1805	0.32840323
	Worker (foraging for pollen)	>18	0	43.5	0.041	7.184265	0.23175048
	Worker (foraging for nectar)	>18	0	292	0.041	48.186765	1.55441177
	Worker (maintenance of hive in winter)	0-90	0	29	2	5.115	0.165

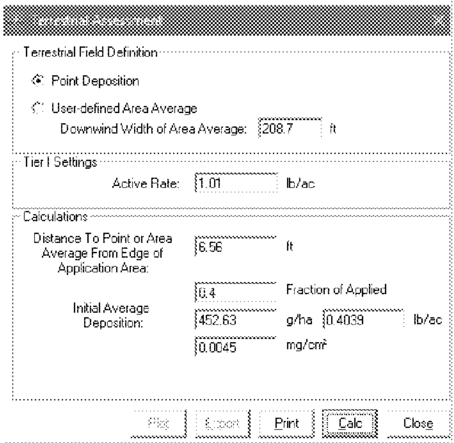
	Drone	>10	0	235	0.0002	38.77503 3	1.25080752
	Queen (laying 1500 eggs/day)	Entire lifestage	525	0	0	0.86625	0.02794355

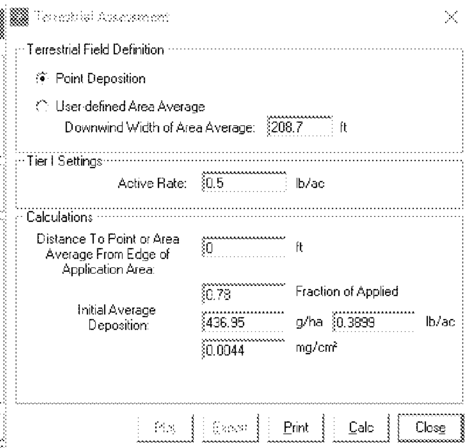
AgDrift Output:
Aerial Applications:
Fine Droplets:



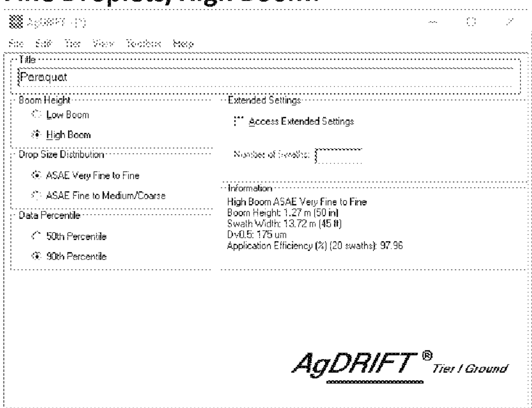
Coarse Droplets:

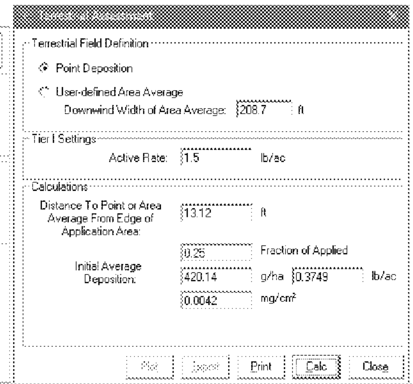


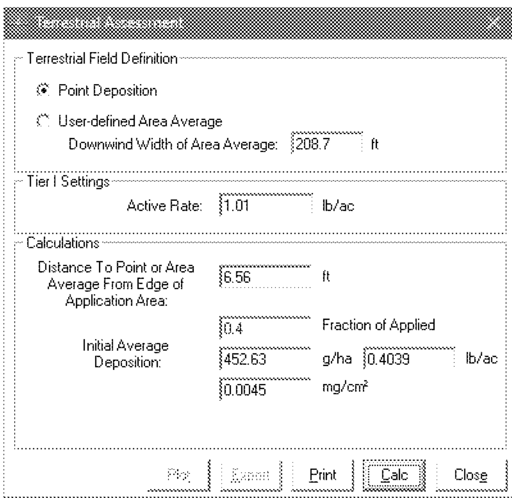


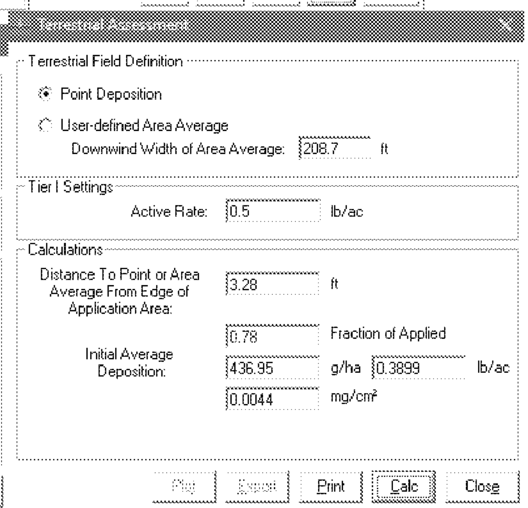


Ground Applications:
Fine Droplets/High Boom:









Coarse Droplets/Low Boom: